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EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY: CLINICAL APPLICATION AND MEDICARE PHYSICIAN PAYMENT

Jonathan A. Showstack, M.P.H.
Eliseo J. Perex-Stable, M.D.
Eric Sawitz, M.D.

Institute for Health Policy Studies
and Division of General Internal Medicine
University of California, San Francisco

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ABSTRACT

Extracorporeal shock wave lithotripsy (ESWL) is the latest in a series of new methods developed over the past decade to treat upper urinary tract stones. Its noninvasive nature, and relatively low morbidity, make ESWL an attractive alternative for removing stones in the upper urinary tract. It is estimated that the projected national demand for ESWL requires between 17 and 106 lithotripters, depending on indications for the procedure and volume of use of each lithotripter.

As Medicare attempts to lower its costs, new methods of paying physicians are being considered. The alternative physician payment mechanisms include changes in current "usual, customary, and reasonable" payment, fee schedules, payment for an episode-of-illness, and capitation payment. Each of these, and other, methods of paying physicians is discussed in this report in the context of its effects on the quality of, access to, and costs of ESWL. It is concluded that the relatively limited need for ESWL, and the high costs of the procedure, will likely produce effects on quality, access, and costs that are similar in many ways for each of the various physician payment alternatives.

Two key issues emerge when considering alternative physician payment mechanisms and their effect on the use of ESWL. These issues are the potentially large effect on the quality, access, and cost of care for Medicare beneficiaries of the absolute level of payment for ESWL, and the question of whether ESWL presents such unique circumstances that separate arrangements with providers for this procedure should be considered by Medicare (similar to Medicare payment for renal dialysis.)

The answers to several as yet unresolved clinical, economic, and organizational questions are needed before the ultimate cost effectiveness of ESWL can be judged. Clinical questions include the effect on the kidney of multiple ESWL treatments, the effect on stone recurrence rates of the possible deposit in the kidney of small stone fragments, and the criteria for the use of ESWL. A central economic question is the effect on the costs and use of ESWL of the development of less expensive methods of treating upper urinary tract stones. Finally, the relationship between community urologists and local ESWL centers is a particularly important organizational question since the decision to refer a patient to an ESWL center has major potential consequences for quality, access, and costs.

It is concluded that ESWL appears to be a useful new technology that is likely to become the standard of care for the treatment of many types of upper urinary tract stones. The future of ESWL, and the quality of, access to, and costs of care of upper urinary tract stones for Medicare beneficiaries, depend on a variety of clinical, economic, and organizational factors, many of which are beyond the direct control of clinicians, patients, payers for medical care, or policymakers.

INTRODUCTION

As new medical technologies are developed and introduced into practice, third-party payers for medical care must decide whether a technology is an accepted part of clinical practice, and, if it is, how much will be paid to physicians and hospitals for performing the technology. This report discusses physician payment for the performance of new technologies in the context of the introduction of Extracorporeal Shock Wave Lithotripsy (ESWL), a new method to treat stones in the upper urinary tract. Among the issues discussed are the epidemiology of urinary tract stones, the variety of currently available treatment methods that may be affected by the introduction of ESWL, the theoretical demand for ESWL, methods used by third-parties to decide on physician payment for new technologies, the economics of ESWL, and how different physician payment mechanisms that might be used by Medicare may affect the use of, and access to, ESWL by Medicare beneficiaries.

This report will become part of a larger report of the Office of Technology Assessment (OTA), United States Congress, on Medicare physician payment and ESWL. Because analyses by others will also become part of the OTA report, we have limited our main discussion to clinical and physician payment issues, although for the sake of clarity we touch upon a variety of other issues. Our brief discussion of these other issues should not be taken to imply that they are unimportant. Because ESWL is not yet in wide use, much of the discussion is theoretical in nature, and must, of necessity, include many assumptions and projections.

Extracorporeal Shock Wave Lithotripsy presents many interesting and unique questions for clinicians, patients, economists, and policy makers. As described below, ESWL is likely to become the treatment of choice for many types of upper urinary tract stones, but its high cost and limited availability, and the relatively limited need for the procedure, lead us to conclude that the economics of ESWL might be quite different from the economics of many other new technologies. It is possible that ESWL's high fixed and variable costs, a projected national need for only approximately 17 to 106 lithotripters, and the recent trend towards prospective payment, may make ESWL one of the first "big ticket" technologies to be regionalized from the start because of economics, rather than because of health planning. Its relative high cost may also hasten the development of other lower cost means of treating urinary tract stones.

Treatment of urinary tract stones has changed rapidly over the past decade. The current form of ESWL is likely to evolve and other new methods of treating stones developed. Extracorporeal Shock Wave Lithotripsy was chosen for analysis as an example of a new, potentially cost-saving, but very costly technology. Since predicting future technological developments, and their economic and clinical costs and benefits, is difficult at best, we describe the current treatment of urinary tract stones, and ESWL as it exists today, in the generic sense of a costly new technology that appears to be useful clinically. As described below, ESWL co-exists with a variety of other useful methods of treating urinary tract stones. Future clinical and technological developments are likely to expand the array of services that urologists and other physicians use to care for patients with urinary tract stones.

Extracorporeal shock wave lithotripsy is currently being developed to treat gall stones. If and when this treatment is approved by the Food and Drug Administration, and paid for by third-parties, a whole array of new issues will occur. For example, the economics of ESWL might change dramatically, with potentially higher volume use of the equipment producing lower costs per procedure, and with gastroenterologists and other internists using the equipment. As with most analyses of medical technologies, new developments may so change the use and other characteristics of the technology that the analysis becomes irrelevant. Since this new development would radically change the entire analysis in this report, and since there may be technical or other barriers to using ESWL for gall stones, we have chosen not to speculate, but rather discuss ESWL only in its role as a treatment for urinary tract stones.

SECTION I

URINARY TRACT STONES: CLINICAL ISSUES

OVERVIEW

This section presents the clinical information necessary for the economic analysis to follow. Medical terminology is used in order to summarize information adequately for the clinician reader, but the essential issues are discussed in nonclinical terms.

After a brief orientation to the anatomy of the urinary tract, with special attention to location of stones, data concerning the incidence of urinary tract stones in the United State are reviewed. The true frequency of urinary tract stones in the United States must be estimated because exact figures are not available. Information available from population-based samples is limited and the use of hospital discharge data may be biased.

A second epidemiological issue discussed is the natural history of a first episode of a urinary tract stone. Although recurrences are common, the symptom-free period is variable and may be as long as ten years or more. Thus, identification of metabolic factors that predict recurrence and formulation of a longer-term preventive management plan are important.

Therapeutic alternatives available in the management of urinary tract stones are described. Medical management of acute episodes is the standard initial approach but several surgical therapies are also available. When stones cause severe complications or persistent symptoms, open surgical procedures have been the intervention of choice for many years. The development of improved transurethral techniques and the perfection of percutaneous techniques have made open surgery nearly obsolete. The efficacy and safety of electrohydraulic and ultrasonic lithotripsy are described and compared to standard open surgery. Less established modalities, such as percutaneous chemolysis of stones, are also discussed.

The process of, and physical setting for, ESWL are described. The data published in English on clinical efficacy are reviewed with special attention to definition of outcomes. The destruction of urinary tract stones is used uniformly in the literature as the major outcome of ESWL and little attention has been focused on symptom resolution, preservation of kidney function, and stone recurrence rates. The reported clinical experience in the United States supports the notion that ESWL is an effective method of eliminating urinary tract stones. The procedure also appears to be quite safe, especially in comparison to open surgery. The role that ESWL should have in the management of urinary tract stones is discussed. This technology is not a "magic bullet" against urinary tract stones, but has a definite role in many cases as a substitute for open surgery or percutaneous lithotripsy.

Finally, projections of the demand for ESWL are made. Relatively poor information on the incidence of urinary tract stones, and the undefined indications for ESWL, may limit the accuracy of these estimates of demand. The number of lithotripters that would meet the projected range of demand is estimated to be between 17 and 106 units, depending on volume of use of each unit and the criteria used to select patients.

ANATOMY OF THE URINARY TRACT

The urinary system can be thought of as a series of connected structures that filter, collect, channel, and store urine. Blood is filtered in the substance of the kidney. Urine from each microscopic filtering unit drains into the renal calices, finger-like protrusions of the hollow core of the kidney, which is called the renal pelvis. The renal pelvis drains into the ureter, a pencil-thin channel leading to the bladder. A fibrous capsule surrounds and protects each kidney.

Stones tend to locate at specific sites in the urinary tract. A renal calix is a natural alcove where stones may lodge and grow. Because there are numerous calices, urine flow may not be obstructed and, in fact, the stone may be asymptomatic. Larger stones may occur in the renal pelvis and grow to virtually mold themselves to the inner contours of the pelvis and calices. Such stones are called "staghorn" because of their obvious and dramatic appearance on X-ray. Despite their size and location, urine flow may not be compromised, although most such stones will require removal by open surgery on the kidney (nephrolithotomy) or by a percutaneous (through the skin) approach.

The junction between the renal pelvis and the ureter is a third common site; these stones can also be reached and removed by surgery (nephrolithotomy). The diameter of the ureter tapers slightly at approximately one-third of its length where the ureter crosses blood vessels. Migrating stones may get "stuck" at this point, for which several approaches can be used. Basket or forceps removal can be attempted "from below," that is, an instrument can be passed through the urethra and the bladder up into the ureter (a transurethral approach). Sometimes direct contact is not necessary since mechanical dilation of the ureter may allow passage of the stone; if this does not occur, the stone may be grasped and removed. Stones that are stuck at the upper part of the ureter or at the junction of the renal pelvis and ureter may be removed by a percutaneous approach. A tube is passed into the renal pelvis through a small incision in the lower back and a variety of techniques may be used to remove the stone. Failing the transurethral and percutaneous approaches, ureterolithotomy (surgery on the ureter) may be necessary. This requires locating and opening the ureter through an abdominal or lower back incision, removing the stone, and closing the ureter. Occasionally, a transuretheral and an open (either ureterolithotomy or nephrolithotomy) approach are used concurrently to locate the stone and possibly remove small leftover fragments. Stones can also be found in the bladder or at the junction of the bladder and ureter (uretero-vesicular junction); these usually pass spontaneously or can be removed transurethrally and open surgery is rarely required.

Symptoms related to stone disease are varied. Stones may be discovered accidentally at autopsy or on X-rays. Stones that obstruct the flow of urine significantly may cause "upstream" swelling of the ureter or the kidney (hydroureter or hydronephrosis) that can endanger the kidney, with or without dramatic symptoms. On the other hand, small stones in the ureter can cause excruciating pain ("colic"), bloody urine (hematuria), or both.

Treatment decisions are related to symptoms, duration, and loss of kidney function. Today, urologists will usually treat acute symptoms conservatively with analgesics, and fluids to flush out the stone. A delay in definitive therapy may allow spontaneous passage of the stone or a decrease in the swelling and inflammation. Acute hydronephosis and/or infection demand more immediate therapy.

Open surgery may be used for stones located in the ureter, in the renal pelvis, and in the calices. Transurethral approaches can be attempted for stones in the lower part of the urinary tract. Percutaneous approaches are semi-open procedures that allow passage of instruments that can visualize and remove stones, and may be used for stones in the ureter and above. They require much smaller skin incisions than open procedures and may even be performed under local anesthetic. Sometimes an opening is created at one sitting; then, after bleeding and spasm are controlled, the stone can be located and removed at a later time. The percutaneous approach is best suited for relatively small stones that are easily reached.

EPIDEMIOLOGY OF URINARY TRACT STONES

Urinary tract stones have been present for thousands of years, but industrial development is associated with an increased incidence in location in the kidney and upper ureter. Bladder stones are common in developing countries and rare in industrialized nations; the converse is true for kidney and ureteral stones. Affluence, sedentary lifestyle, and male sex have been associated with an increased risk of stone formation, but the reasons are not clear. Dietary changes (increased protein) and decreased fluid intake are attractive, but unproven, hypotheses that may partly explain the observed associations with stone disease (Coe, 1978).

Data on the incidence of urinary tract stone disease in the United States are limited. The existing literature may not be comparable because of variation in methods and definitions of stone incidence. The first estimate of urinary tract stone incidence was obtained from a survey of U.S. hospitals in 1952 (Boyce, Garvey, Strawcutter, 1956). Approximately 4,000 questionnaires were mailed (80 percent of all registered hospitals), but only 537 (11 percent of mailed) replies were completed adequately for the 1948-1952 five-year period. A discharge diagnosis of urinary tract stones was used to define a case, and incidence was estimated at 94.7/100,000 persons for 1952. A similar questionnaire survey was mailed to every hospital in the United States in 1975 requesting information on the total number of discharges with the diagnosis of urinary stones for 1974 (Sierakowski, Finlayson, Landes, et al., 1978). The response rate improved slightly to 27.2 percent--1765 adequately completed questionnaires out of more than 6500 mailed. The annual incidence of urinary tract stones in the population was estimated at 164.1/100,000 persons using the 1970 U.S. census. This represents a 73 percent increase over the 22 year period.

The major limitations of these two studies are the low response rates, which may introduce biases, and the sole reliance on hospitalization data. The repeated hospitalizations of patients with recurrent stones were not corrected for and this may inflate the incidence rate. On the other hand, at least 50 percent of urinary tract stone patients do not require hospitalization (Johnson, Wilson, O'Fallon, et al., 1979; Hiatt, Dales, Friedman, et al., 1982). Thus, on balance, these studies may estimate the true incidence of stone disease fairly accurately. Generalizability of these findings requires further substantiation from other sources.

The unique database available to the Rochester Epidemiological Project has provided the best available estimates of the incidence of urinary tract stones (Johnson, Wilson, O'Fallon, et al., 1979). A 25-year study of Rochester, Minnesota residents, showed an increase in the annual age adjusted incidence of urinary tract stones from 78.5 to 123.6 per 100,000 men for 1950 and 1974, respectively (Johnson, Wilson, O'Fallon, et al., 1979). The incidence in women remained stable for this period at 36.0/100,000. These data represent as close to a complete sample as feasible and include diagnoses made in ambulatory as well as in hospitalized patients. The 57 percent increase in incidence rates of urinary tract stones in men supports the observed trend from the hospital surveys.

The most recent study on the epidemiology of urinary tract stones was reported from the Kaiser Foundation Health Plan in Northern California (Hiatt, Dales, Friedman, et al., 1982). The outpatient clinic diagnostic information from the San Francisco Medical Center was examined for "new or recurrent" stones covering the period 1970-72. The results showed an age adjusted incidence rate of 122/100,000 members--181/100,000 men and 59/100,000 women (Hiatt, Dales, Friedman, et al., 1982). A second calculated incidence rate was based on hospitalization discharge diagnoses for the entire Northern California Kaiser Foundation Health Plan from 1971-75. The age adjusted annual rate for urinary tract stones was 36/100,000 members--52/100,000 men and 19/100,000 women. Rates were twice as high in white persons as they were in blacks and Asians. An inverse correlation was found between a history of urinary tract stones and the educational background of the person (Hiatt, Dales, Friedman, et al., 1982).

Urinary tract stones peak in incidence in men between 40 and 60 years of age and a stable rate persists through the seventh decade (Johnson, Wilson, O'Fallon, et al., 1979). A decline in incidence in men and women older than 70 years of age has been observed in both the Rochester and Kaiser studies (Johnson, Wilson, O'Fallon, et al., 1979; Hiatt, Dales, Friedman, et al., 1982). The overall incidence of urinary tract stones in persons older than 65 years of age is therefore similar to that found in the general population.

Thus, urinary tract stones are common, appear to be increasing in incidence, and affect men during the productive period of their lives. The National Center for Health Statistics (NCHS) has provided additional indications that the incidence of a primary discharge diagnosis of urinary tract stones stones has increased to 142/100,000 persons (207/100,000 men) for 1983 (U.S. NCHS, 1983). Data from the Commission on Professional and

Hospital Activities (CPHA) have produced similar estimates of incidence with considerable geographic variation (Commission on Professional and Hospital Activities, 1983). As noted above, counting discharges overestimates the incidence of "hospitalizable" stone disease because of possible multiple admissions for the same stone.

The lifetime incidence of urinary tract stone disease probably varies by sex, ethnicity and socioeconomic factors, but for men it has been estimated at 10 percent by several groups in the United States (Boyce, Garvey, Strawcutter, 1956; Sierakowski, Finlayson, Landes, et al., 1978; Johnson, Wilson, O'Fallon, et al., 1979). The Southern states continue to show increased incidence rates when hospital data are compared and thus the designation of a "stone belt" may be appropriate. One random sample of Scottish residents reported a stone disease incidence of 3.8 percent (Scott, Freeland, Mowat, et al., 1977). A summary of reported incidence rates in the United States is presented in Table 1.

One episode of urinary tract stone disease may cause significant morbidity and the reported natural history indicates that an estimated 50 to 70 percent of patients have a second stone (Johnson, Wilson, O'Fallon, et al., 1979). Early reports suggested that 85 to 90 percent of patients with a single stone passed spontaneously never developed another one (Garvey, Boyce, 1956; Baker, Connelly, 1956), but subsequent studies have contradicted this. A retrospective evaluation of 538 patients with upper urinary tract stone disease for a minimum of 10 years reported that 75 percent had recurrences over a mean period of 18.5 years (Williams, 1963). Marshall and colleagues followed 416 patients at a London stone clinic for a

Table 1

Incidence of Urinary Tract Stones

Population Studied (Year)	Incidence Rates (per 100,000)		
	Total	Men	Women
Discharge Diagnoses (1952)[*]	94.7	-	-
Discharge Diagnoses (1974)[†]	164.1	-	-
Rochester, Minnesota (1950)[¶]	58.7	78.5	43.2
Rochester, Minnesota (1974)[¶]	73.4	123.6	32.4
San Francisco Kaiser Outpatients[§] (1970-72)	122	181	59
Northern California Kaiser Discharge Diagnoses[§] (1971-75)	36	52	19

[*] Boyce, Garvey, Strawcutter, 1956

[†] Sierakowski, Finlayson, Landes, et al., 1978

[¶] Johnson, Wilson, O'Fallon, et al., 1979

[§] Hiatt, Dales, Friedman, et al., 1982 mean period of 7.6 years and reported that 36.1 percent of the sample developed a second stone (Marshall, White, De Saintonge, et al., 1975). The Rochester study sample had a symptomatic recurrence rate of 30.0 percent for women and 45 percent for men over 14 years of follow-up (Johnson, Wilson, O'Fallon, et al., 1979). The recurrence rates peaked in the first year with 15.9 percent of men and 12.4 percent of women developing a second stone; subsequent annual recurrence rates remained constant at 3.7 percent for men and 2.0 percent for women (Johnson, Wilson, O'Fallon, et al., 1979).

The etiology of urinary tract stones influences the observed recurrence rate. Primary hyperparathyroidism, renal tubular acidosis, cystinuria, primary hyperoxaluria, recurrent infections, and sarcoidosis all play a role in stone formation (Coe, 1978). Seventy to 75 percent of all stones in the United States are calcium, and a minority of patients have a systemic disorder as the cause. Metabolic evaluations of calcium stone formers show that up to 60 percent have hypercalciuria and/or hyperuricosuria (high concentrations of calcium and uric acid, respectively, in the urine) as contributing factors (Coe, 1978). The presence of hyperuricosuria alone appears to predict a more severe course of stone formation with comparatively short inter-event intervals (Coe, Keck, Norton, 1977). The risk of recurrence peaks during the first two years but may increase again at eight years after the first calcium stone (Coe, Keck, Norton, 1977). Coe and colleagues have reported an overall average interval to the second stone of 4.5 years and this group believes that recurrences approach 100 percent if patients are followed for a long enough time (Coe, 1978; Coe, Keck, Norton, 1977). Medical treatment of the metabolic abnormalities in calcium stone formers decreases the recurrence rates in patients with frequent episodes (Coe, 1977; Pak, Peters, Hurt, et al., 1981; Elomaa, Ala-Opas, Porkka, 1984).

Struvite stones are found in 15 to 20 percent of patients with urinary tract stone disease and are usually associated with recurrent infections. Although medical therapy has had some encouraging results, drug side-effects and lack of efficacy prevents wider applicability (Williams, Rodman, Peterson, 1984). Prevention of struvite formation by effectively acidifying the urine is an important secondary maneuver after removal (Smith, 1984).

Uric acid stones cause 5 to 10 percent of urinary tract stones in symptomatic patients and an identifiable metabolic disorder is often present. Dietary manipulations in limiting animal protein intake may help. Allopurinol therapy is effective for recurrent uric acid stone formers. Cystine stones are relatively uncommon, occurring in only 1 to 2 percent of stone formers.

Recurrent urinary tract stones containing calcium have become preventable over the past decade (Coe, 1981). Evaluations of calcium stone formers have identified the presence of metabolic risk factors including hypercalciuria and/or hyperuricosuria in 60 percent (Coe, 1978). Treatment with thiazide diuretics and/or allopurinol have been shown to significantly alter the natural history of recurrent stone formers (Coe, 1977; Pak, Peters, Hurt, et al., 1981; Elomaa, Ala-Opas, Porrka, 1984). Thus, patients treated for urinary tract stones should be evaluated thoroughly for metabolic abnormalities in order to prevent recurrent stone formation.

The importance of dietary management of calcium stones has been overlooked in recent years (Smith, Van Den Berg, Wilson, 1978). High fluid intake in order to guarantee a minimum urine output of 2 liters per day may decrease recurrence rates of calcium stones in up to 60 percent of patients (Hosking, Erickson, Van Den Berg, et al., 1983). A moderate calcium restriction of 400 to 600 mg per day may be useful in patients with absorptive hypercalciuria. Other patients with idiopathic calcium stones should avoid an excess of 1 gram of calcium intake per day (Pak, Smith, Resnick, 1984). Dietary restrictions of oxalate, animal proteins, sodium and phosphate are occasionally useful adjuncts to medical management.

THERAPEUTIC ALTERNATIVES IN THE MANAGEMENT OF URINARY TRACT STONES

The majority of symptomatic urinary tract stones are sufficiently small to pass spontaneously. The size and location of a stone at the time of clinical presentation helps to predict its often erratic behavior. Large stones found in the upper urinary tract at the time of diagnosis are less likely to pass spontaneously. In one series of 292 cases, 91 percent of stones 5 mm or smaller passed spontaneously with the help of endoscopic procedures, but 60 percent of larger stones required surgery (Fox, Ryan, Raper, 1965). Other studies have estimated that stones over 7 mm in size impacted in the upper ureter rarely pass spontaneously (Sandegard, 1956). Stones in the upper urinary tract that are too large to pass spontaneously involve the greatest risk of serious complications.

Conservative medical management of symptomatic stones provides adequate therapy in up to three-quarters of cases. Oral or parenteral analgesics for relief of pain are indicated. Smooth muscle relaxants have been used to relieve spasm and to promote passage of the stone, but these are of doubtful value. Traditionally, a high fluid intake has been considered helpful in inducing stones to move. Evidence of infection above the stone, refractory pain, ureteral obstruction, and anuria (lack of urine flow) are considered absolute indications for stone removal (O'Flynn, 1983). Stones that have not passed, and remain symptomatic, after six weeks of conservative therapy should be considered for removal.

Major surgery on the urinary tract for removal of stones carries a significant morbidity and a small risk of death. Ureterolithotomy is successful in removing stones in 99 percent of cases and failures are usually related to surgical difficulties in locating the ureter and/or the stone (O'Flynn, 1983). In one series of 445 patients undergoing ureterolithotomy, 18.4 percent had surgical complications, including three deaths (Furlow, Bucchiere, 1976). Hospitalization for an uncomplicated ureterolithotomy averages ten days and the convalescence usually lasts about six weeks.

Indications for surgical removal of stones lodged in the kidney are less clear. Persistent pain, associated infection and obstruction are more common with stones located in the ureter than with stones located in the kidney. Struvite stones associated with recurrent infections are an exception and surgery has been the standard of care (Smith, 1984). Partial nephrectomy (removal of part of the kidney) for stone removal is associated with overall morbidity rates as high as 40 percent and mortality in one series of 96 patients was 1.7 percent (Coleman, Witherington, 1979). A retrospective review of 951 open surgical procedures reported an associated mortality rate of 0.6 percent; serious complications, including hemorrhage in excess of one liter, were found in an additional 13 percent of cases (Boyce, 1983). A recent series of 100 patients undergoing nephrolithotomy reported that 4 percent had stones left behind (Brannen, Bush, Correa, et al., 1985).

Recurrence rates of symptomatic stones vary according to the type of stone. Struvite stones recur in between 40 and 60 percent of patients (Brannen, Bush, Correa, et al., 1985; Williams, Rodman, Peterson, et al., 1984; Martinez-Pineiro, Gaston de Iriarte, Armero, 1982) and the rate of recurrence in natural history studies of calcium stones would be expected to apply after surgical intervention (Williams, 1963; Marshall, White, De Saintonge, et al., 1975; Coe, Keck, Norton, 1977).

Traditional transurethral approaches may be able to manipulate a stone in the lower ureter so that open surgery is avoided. Simple catheterization (insertion of a tube) of the ureter, with or without dilatation, induces spontaneous passage of stones in 21 to 37 percent of cases (O'Flynn, 1983). Transurethral meatotomy (opening the mouth of the ureter where it enters the bladder) is indicated when the stone is impacted at the ureteral-vesical junction, but this maneuver is not helpful for removal of stones at a higher level. Stones in the lower third of the ureter may be extracted transurethrally by use of a wire or nylon basket. The success rate of this procedure varies, but has been reported to be between 69 and 77 percent in two series of 173 and 121 patients, respectively (O'Flynn, 1983; Lyon, Huffman, Bagley, 1984). A basket extraction technique using a specially designed angioplasty balloon to dilate the ureter had a reported success rate of 95 percent in 39 patients (Rutner, 1984). Open surgical procedures are required in 5 to 10 percent of patients after attempted stone removal by transurethral manipulation (O'Flynn, 1983; Lyon, Huffman, Bagley, 1984; Rutner, 1984). The uncomplicated patient is hospitalized for approximately five days after successful transurethral extraction of a stone.

Complications of transurethral extraction techniques include perforation at the ureterovesical junction, damage to ureteral integrity, stone movement into the kidney, renal colic (severe pain), bleeding, and infection. Evidence of bleeding is present in 10 to 15 percent of cases at the conclusion of the procedure, but this is usually no longer demonstrable 48 hours later (Lyon, Huffman, Bagley, 1984). Routine use of prophylactic antimicrobials limits the rate of significant infections to less than 1 percent.

Endourologic equipment and techniques developed during the past 15 years allow access to stones in the upper urinary tract without resorting to open surgery. Percutaneous nephrostomy was first described in 1955 (Goodwin, Kasey, Woolf, 1955), but the technique was not widely applied to the therapy of urinary tract stones until the late 1970s (Stables, Ginsberg, Johnson, 1978). Access to the renal collecting system is achieved by direct puncture under fluoroscopic or ultrasound guidance; a catheter is inserted through the needle and a guide wire follows to maintain the tract. The nephrostomy tract is then progressively dilated, frequently under general anesthesia. Nephrostomy, dilatation, and stone extraction have been accomplished as a one stage procedure, but bleeding after dilatation often obscures visibility, requiring a 24 to 48 hour delay. The development and modification of equipment that destroys stones prior to removal have increased the applicability of percutaneous nephrostomy.

Transurethral electrohydraulic lithotripsy is a highly effective means of bladder stone removal and it has become an accepted practice (Mitchell, Kerr, 1977). The electrohydraulic lithotripter releases high impulse discharges from an electrode at the tip of a flexible stone probe. The shock waves generated are of sufficient force to disrupt the hardest stone. Application of electrohydraulic lithotripsy to percutaneous techniques has been limited to small series (Clayman, Surya, Miller, et al., 1984; Goodfriend, 1984), and there is far less reported experience than for ultrasonic lithotripsy (see below). The electrohydraulic lithotripsy probe must not be used 5 mm or closer to soft tissue or severe damage will result (Miller, 1983). A British group has reported the safe removal of stones in 17 patients without a single perforation, and, in their experience, electrohydraulic lithotripsy is superior to ultrasonic lithotripsy for all but very soft stones (Miller, Wickham, 1984).

Percutaneous ultrasonic lithotripsy was first performed in 1977 (Kurth, Hohenfellnar, Altwein, 1977), but clinical experience has been greatly expanded since that time (Brannen, Bush, Correa, et al., 1985; Clayman, Surya, Miller, et al., 1984; Segura, Patterson, LeRoy, et al., 1983; Brannen, Bush, 1984; Bass, Beard, Cooner, et al., 1985). The ultrasound probe emits high frequency ultrasonic energy that upon direct exposure to the stone has a simple drilling effect. Direct contact of the probe tip and stone is essential for effectiveness of ultrasonic lithotripsy. A suction channel is attached to the hollow probe in order to continuously remove stone fragments (Marberger, 1983). Transurethral application of ultrasonic lithotripsy to bladder stones is effective, but the experience with stones in the ureter and renal pelvis is limited (Huffman, Bagley, Schoenberg, 1984).

The reported experience with percutaneous ultrasonic lithotripsy demonstrates a "learning curve" effect for both efficacy in removing stones and serious complications (White, Smith, 1984; Schoenberg, 1984). Segura and colleagues successfully removed 96 percent of 148 kidney stones and 86 percent of 50 ureteral stones by percutaneous ultrasonic lithotripsy (Segura, Patterson, LeRoy, 1983). Major complications were encountered in 3.2 percent of this series including two patients who required an operation (Segura, Patterson, LeRoy, 1983). A small series of 23 patients had percutaneous ultrasonic lithotripsy for stone removal and the efficacy was 97 percent with one or more sessions, but 8.7 percent had complications severe enough to prolong hospitalization (Brannen, Bush, 1984). The same group subsequently reported their two year experience with 250 consecutive patients and targeted stones were removed in 97 percent of patients. by percutaneous ultrasonic lithotripsy (Brannen, Bush, Correa, et al., 1985). A repeat nephrostomy was performed in 20 patients (8 percent) and an additional 32 patients (13 percent) required an additional procedure (e.g., transurethral manipulation) to remove the stone (Brannen, Bush, Correa, et al., 1985). The overall complication rate was 6.8 percent, but significant delayed bleeding occurred in eight patients (3.2 percent) and three of these required angiographic embolization to control hemorrhaging (Brannen, Bush, Correa, et al., 1985). A community hospital urology group had an 87 percent success rate in removing stones from 38 patients by percutaneous ultrasonic lithotripsy and the overall complication rate was 7.8 percent (Bass, Beard, Cooner, 1985).

The nephrostomy procedure and tract dilatation in order to pass the nephroscope are associated with the majority of significant complications of percutaneous ultrasonic lithotripsy. Stables reviewed the experience with 1207 patients and reported a 4 percent incidence of significant complications, mostly hemorrhage and infection, and one death (Stables, 1982). In general, most problems with nephrostomy tubes are mechanical, displacement or blockage; failed attempts at placement are rare (Roven, Rosen, 1984). The Mayo Clinic's experience with 1032 percutaneous manipulations for stone removal reported a delayed bleeding rate of nearly 1 percent from significant vascular injuries (Patterson, Segura, LeRoy, 1985). Seven patients were treated successfully with transcatheter embolization techniques, two resolved spontaneously with observation, and one underwent an emergency flank exploration resulting in nephrectomy (Patterson, Segura, LeRoy, 1985). A bleeding disorder is an absolute contraindication to percutaneous lithotripsy and use of aspirin or other anti-platelet agents leads to postponement of the procedure for at least one week (Segura, LeRoy, 1984). Function of the operated kidney was not observed to deteriorate three months after percutaneous ultrasonic lithotripsy in 15 patients examined by differential creatinine clearances (Mayo, Krieger, Rudd, 1985).

Perforations of the collecting system usually heal spontaneously after 24 to 48 hours and water intoxication has been reported after irrigation with hypotonic solutions required during percutaneous ultrasonic lithotripsy (Brannen, Bush, Correa, et al., 1985; Brannen, Bush, 1984).

Percutaneous chemolysis (application of drugs through an opening in the skin) of stones in the kidney has not been widely accepted as a therapeutic alternative. The prolonged duration of irrigation therapy with percutaneous administration of drugs in the hospital limits the usefulness of the technique. Pfister and Dretler have maintained that there is a role for percutaneous chemolysis (Pfister, Dretler, 1984). Struvite, apatite, and carbonate stones can be dissolved with an acidic solution, while an alkaline agent will dissolve cystine stones. In the series of 150 patients with symptomatic stones treated by percutaneous chemolysis, complete dissolution was achieved in 70 percent and another 15 percent had only tiny fragments remaining (Pfister, Dretler, 1984). Progress was monitored every 3 to 4 days by X-rays and the total duration of irrigation was one to four weeks (Pfister, Dretler, 1984).

EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY : DEFINITION AND PROCESS

Extracorporeal shock wave lithotripsy is the most recent development in the treatment of upper urinary tract stones. It is a technique that uses shock waves generated outside the body to disintegrate stones.

Developed in the Federal Republic of Germany by the Dornier Corporation, clinical application of ESWL was carried out by Christian Chaussy and collaborators with the support of the German government (Chaussy, 1982).

The technique has been used in West Germany since 1980 and the first six devices were installed in the United States in 1984. After evaluation of the results at the investigating clinical centers, in December, 1984 the Food and Drug Administration (FDA) approved the device for general use. There are plans to install 25 more lithotripters in the United States in 1985.

The physical properties and energy content of shock waves differ from ultrasonic waves, which are used in other techniques for destroying stones. Shock waves have a single pressure pulse with a steep onset and gradual decay, in contrast to ultrasonic waves, which are characterized by a train of alternating compressions and expansions (Chaussy, 1982). In ESWL, shock waves are generated outside of the body and transmitted through a water bath to the stone in the kidney or upper ureter. Immersion in the water bath allows the shock wave to pass from the generator to the patient without resulting in tissue damage since water and tissue have similar acoustic impedance properties. The water temperature, gas content, and conductivity are controlled by a treatment system in the lithotripter.

The shock waves are generated by an underwater spark from an electrode located at the first geometric focus of an ellipsoidal reflector. The stone has to be positioned on the second focus of the ellipsoid reflector, which is the point of highest energy density. A two-dimensional radiographic scanning system, using two X-ray units, and a patient positioning system ensure proper location of the stone. The force generated by the shock wave is concentrated on a spherical area 2 cm in diameter (the second focus). A large pressure zone is created as the shock wave passes from tissue or urine into the stone. This pressure exceeds the strength of the stone material and causes its destruction. Repeated shock wave applications result in the fragmentation of a stone into small pieces (2 mm or less), which normally are passed spontaneously.

Each ESWL treatment uses approximately 1000 to 1500 shocks. The shocks are synchronized with the patient's electrocardiogram to be delivered during the heart's refractory period; this avoids the complications experienced in the early trials of triggering arrhythmias of the heart (Chaussy, 1982).

Urologists have been the principal physicians performing ESWL. A significant proportion of patients treated by ESWL requires a percutaneous or transurethral procedure to remove stone fragments that were not crushed or passed spontaneously. Thus, the involvement of a urologist in administration of ESWL is advisable. Anesthesiologists have also participated in most treatment sessions, although nurse anesthetists may be used instead. The majority of ESWL treatments may be performed eventually under epidural anesthesia, but much of the reported early experience used general anesthesia. Several of the established ESWL facilities in the United States plan to continue to rely on general, rather than epidural, anesthesia. The technical support and administrative assistance usually necessary for running an operating room are also required.

The location of a lithotripter may be determined in part by geography and the population to be served. Hospitalization will continue to be necessary for at least 20 to 30 percent of patients treated and to monitor pain and hematuria (bloody urine). An estimated 10 to 30 percent of patients will require a second procedure (percutaneous nephrostomy or transurethral) and thus will need the services of a urologist skilled in the use of these techniques. Thus, the location of a lithotripter should be at or near a facility providing these services.

A prospective patient for ESWL is evaluated by a urologist (or another physician) well before the procedure is performed, usually as an outpatient. The patient is then scheduled for ESWL and admitted to the hospital the day before the procedure. (ESWL may be used in the future predominantly as an outpatient procedure.) On the day of ESWL, a urethral catheter may be placed, an intravenous line started, and preparation for anesthesia is completed. The urologist supervises the placement of the patient in the bath and monitors the process. This includes alignment of the patient, with careful attention to the location and size of the stone. The urologist decides on the duration of the procedure, based on the stone's disintegration, the patient's condition, and the limits of the equipment.

Currently, a urologist, an anesthesiologist or nurse anesthetist, and a technician are present during the procedure (a radiologist is rarely used). From start to finish, the entire process takes approximately 45 minutes to 1 hour. After the procedure, the urologist evaluates the success of the procedure based on several factors, including kidney function, symptoms (pain, hematuria), and the recovery of stone material in the urine. The urologist also attends to the patient's general recovery from the procedure and from the anesthesia. At a later time, the urologist will assess the need for continued therapy, possibly including a second ESWL session, open surgery, or other procedures.

Thus, ESWL is, in many ways, analogous to surgery in the sense that there is a pre-procedure evaluation phase, the undertaking of the procedure itself (which involves some risk to the patient), an immediate post-procedure phase that requires careful monitoring of the patient, and a later phase that requires reassessment and possibly continued therapy. It can be expected, however, that in the majority of cases no immediate surgery would be performed subsequent to ESWL. As described below, cardiac and hemodynamic complications have been reported, and pain and hematuria are common. Urinary obstruction and/or kidney failure may occur due to the stone disease itself, but it has not been reported to be a consequence of ESWL. The failure of the procedure, including only the partial disintegration of the stone, might require surgery, although surgery would not be needed immediately.

ESWL Clinical Experience: Efficacy

Chaussy and collaborators have reported their experience with ESWL from 1980 to 1983 in five English language publications (Chaussy, Brendel, Schmiedt, 1980; Chaussy, Schmiedt, Jocham, et al., 1982; Chaussy, Schmiedt, Jocham, 1983; Chaussy, Schmiedt, 1984; Chaussy, Schmiedt, Jocham, et al., 1984). The initial exclusion criteria in selecting patients were: 1) obstruction of the urinary tract; 2) infection of the urinary tract; 3) stones larger than a cherry; 4) insufficient contrast density for precise localizations (the stone couldn't be seen clearly enough on X-ray to position the patient precisely); and 5) patients with other significant medical problems (Chaussy, 1982). Approximately 39 percent of the first 206 patients treated with ESWL had previous surgery on the treated kidney for stone disease (Chaussy, Schmiedt, Jocham, 1983). Selection criteria for inclusion for ESWL treatment were not otherwise described. The severity of symptoms associated with the urinary tract stones in the ESWL treated patients is not discussed in any of the reports.

In 1980 the first description of the clinical experience of ESWL in 23 patients was published. In 20 patients (87 percent) the stones were destroyed by ESWL, and expelled spontaneously; only 2 (8.7 percent) were reported as having renal colic (severe pain) in the process, but hematuria was present in all (Chaussy, Brendel, Schmiedt, 1980). The three failures all required open surgical procedures; two patients with ureteral stones and one with a staghorn stone (Chaussy, Brendel, Schmiedt, 1980). Although general anesthesia was used in 65 percent of patients, 8 of the last 9 patients undergoing ESWL were given only epidural anesthesia. An update was published in 1982 that included the experience with 72 patients (Chaussy, Schmiedt, Jocham, et al., 1982). There was followup on 63 of the patients at three months and 54 (86 percent) had no stones demonstrable on X-ray; five patients (8 percent) had residual stones and four (6 percent) failed ESWL, requiring open surgery (Chaussy, Schmiedt, Jocham, et al., 1982). The third report summarized the experience in 206 patients receiving 221 ESWL treatments. Ninety-eight percent of the patients had renal pelvis or caliceal stones (Chaussy, Schmiedt, Jocham, 1983). Follow-up examination at five months showed that 88.6 percent were free of stones by X-ray and 10.5 percent had residual concretions; all of these 202 patients were free of symptoms. Two patients underwent surgery due to obstruction in the ureter from fragments of stones and an additional two patients with ureteral stones required open surgery (Chaussy, Schmiedt, Jocham, 1983).

A later update reported on 498 patients (Chaussy, Schmiedt, 1983). A three-month post-ESWL evaluation showed 90 percent free of stones, 9 percent with residual stones of small size and only 1 percent (N=4) requiring open surgical procedures (Chaussy, Schmiedt, 1983). The composition of stones treated with ESWL was reported as 80 percent calcium containing, 15 percent struvite, and 5 percent uric acid or cystine, approximately the same as the general population of stones. Successful subsequent treatment of 30 patients with ureteral stones was mentioned and the investigators emphasized that all of these had moved into the ureter six weeks or less before ESWL treatment (Chaussy, Schmiedt, 1983).

Chaussy and collaborators summarized the Munich experience with 945 patients undergoing 1,068 ESWL treatments (Chaussy, Schmiedt, Jocham, et al., 1984). At three months after ESWL, 89.5 percent of patients were free of stones, 10 percent had detectable stones on radiographic evaluation, and 0.6 percent had undergone open surgery. To achieve this efficacy rate adjuvant procedures were necessary in 76 (8 percent) patients; transureteral manipulations were conducted in 33 (3 percent) and percutaneous nephrostomy was necessary in 43 (5 percent) (Chaussy, Schmiedt, Jocham, et al., 1984). One ESWL treatment was sufficient in 87 percent, but 11 percent and 2 percent of patients underwent two and three treatments, respectively (Chaussy, Schmiedt, Jocham, et al., 1984). Although the high proportion of treated patients with previous surgery on the affected side indicates a patient population of recurrent stone formers with severe symptoms, information is lacking on patient selection and severity of symptoms before ESWL treatment. The early exclusion criteria were eventually discarded and the only remaining contraindication noted was "pathologic drainage conditions" below the stone and location inferior to the iliac crest (in the lower part of the ureter) (Chaussy, Schmiedt, Jocham, et al., 1984). More than 100 ureteral stones were treated successfully with ESWL when their presence in the ureter did not exceed six weeks (Chaussy, Schmiedt, Jocham, et al., 1984).

During 1984 more than 7,000 ESWL treatments were performed around the world including about 2,400 procedures at six centers in the United States. The United States experience appears to corroborate the German reports. At Methodist Hospital in Indianapolis, 500 patients have undergone ESWL treatments for stones in the kidney and ureter; only 14 percent were completely stone-free at discharge from the hospital but at three months 75 percent had no radiographic evidence of stones (Lingeman, Newman, Steele, et al., 1985). The proportion requiring secondary stone manipulations was 7.5 percent, but only five patients required a percutaneous approach. Repeat ESWL was necessary in 9 percent. Open surgery for stone removal was necessary in one patient (Lingeman, Newman, Steele, et al., 1985).

The New York Hospital-Cornell University ESWL unit has reported that 80 percent of disintegrated stones pass spontaneously after ESWL (Riehle, Fair, Vaughan, 1985). Approximately 10-20 percent of treated patients require a secondary procedure and the authors have identified Food and Drug Administration (FDA) category B stones as more likely to need these procedures (Riehle, Fair, Vaughan, 1985). These stones include those greater than 2 cm, ureteral location, partial and complete staghorns, and presence of infection.

Another West German group has reported on 750 patients receiving ESWL treatments; stone disintegration was achieved in 99.1 percent, 0.6 percent underwent percutaneous nephrolithotomy and 0.3 percent open surgery (Fuchs, Miller, Bub, et al., 1985). Secondary measures were necessary in 16 percent, including repeat ESWL treatments. Evaluation at three months after ESWL showed that 85 percent of patients were stone-free by plain abdominal X-ray; a second ESWL session was required in 3 percent of cases (Fuchs, Miller, Bub, et al., 1985).

The available data on the world experience to date indicates that 80 to 90 percent of patients are free of stones at three months after ESWL. A secondary procedure is necessary in approximately 10 percent of patients to achieve this degree of success and 10-15 percent will require more than one ESWL session. Recurrence rates for ESWL of new symptomatic stones have not been reported. Also, the role of medical management and preventive measures after ESWL has not been addressed in the literature.

ESWL Clinical Experience: Safety

The early animal experiments and theoretical considerations pointed to several potentially sensitive body tissues that could be seriously harmed by ESWL (Chaussy, 1982). Hemolysis of red blood cells (separation of hemoglobin) has not been reported after more than 1,000 treatments in human beings. Despite early theoretical concerns, bone and intestine have not been affected. The bowel is routinely screened for gas before initiation of

ESWL treatment, but problems of significance have not been encountered (Chaussy, Schmiedt, Jocham, et al., 1984). The gas-water interface of pulmonary tissue makes the lung susceptible to injury from shock waves; however, damage has been avoided by adequate shielding and accurate positioning of the patient (Chaussy, Schmiedt, Jocham, et al., 1984).

Cardiac extrasystoles of atrial and ventricular origin were observed in 80 percent of treated patients during the early ESWL experience. One patient with underlying heart disease developed acute heart failure during ESWL therapy and eventually died (Chaussy, Schmiedt, Jocham, et al., 1984). The has been no evidence of cardiac problems since the equipment has been modified to synchronize the shock waves with the R waves on the patient's electrocardiogram, which is monitored continuously during treatment. This insures that the shock waves reach the heart only when it is actually beating and thus is refractory to further stimulation.

Hemodynamic alterations are present in patients who are immersed and subsequently removed from a water bath (Weber, Chaussy, Madler, et al., 1984). Immersion causes peripheral venous compression (increased blood return) that results in significant increases in right atrial pressure (3 to 16.5 mm Hg), pulmonary capillary wedge pressure (6.5 to 17.5 mm Hg), and cardiac index (2.05 to 2.48 l/min/m2) at 10 to 50 minutes (Weber, Chassy, Madler, et al., 1984). These physiologic changes indicate that the increased workload on the heart may cause high risk cardiac patients to decompensate hemodynamically if immersed in a water bath. Thus, invasive monitoring would be necessary for adequate management. Chaussy and collaborators reported that 4.3 percent of the ESWL treated patients were in the highest operative risk group (Weber, Chaussy, Madler, et al., 1984) and thus at risk for hemodynamic complications. Immersion in a water bath may also limit access to a patient in case of cardiopulmonary arrest or other unforeseen emergencies.

Obviously bloody urine is present in virtually every patient after ESWL treatment. Chaussy's group found only 6 patients (0.6 percent) with subcapsular hematomas (blood located in the potential space between the kidney and its fibrous capsule) on routine ultrasound examination. Blood transfusions were necessary in only two cases and none required surgery (Chaussy, Schmiedt, Jocham, et al., 1984). The Gainesville, Florida, ESWL group studied 15 consecutive patients pre-and post-ESWL with intravenous pyelography (IVP) and magnetic resonance imaging. Four asymptomatic perirenal hematomas were diagnosed on magnetic resonance imaging, although only one patient had a significant drop in hemoglobin. Kidney function, evaluated by renograms and 131I hippurane clearance, was significantly diminished in the patients with hematomas (Hunter, Newman, Drylie, 1985). The 26 percent rate of hematomas reported with magnetic resonance imaging, and the compromised renal function, are of concern and warrant further investigation. The experience at the other U.S. centers using routine ultrasound imaging to look for subcapsular hematomas has been consistent with the German experience and has not confirmed the Gainesville reports.

Chaussy and collaborators undertook an evaluation of renal function in 100 patients after ESWL treatment using bilateral 131I-hippuran clearance as an index (Chaussy, Schmiedt, Jocham, et al., 1984). The process of patient selection was not indicated and followup was possible in 50 of these patients at two years. There was no significant renal impairment observed and, in fact, a 10 percent improvement in clearance was achieved (Chaussy, Schmiedt, Jocham, et al., 1984). Relief of stone-related urinary obstruction probably explains these findings.

Extracorporeal shock wave lithotripsy treatments are painful, and adequate analgesia during the procedure is imperative. The summary of the Munich experience showed that epidural anesthesia was used in three-quarters of patients (Chaussy, Schmiedt, Jocham, et al., 1984), but, possibly because of the treatment of larger stones, the majority of procedures performed in the United States has been done under general anesthesia. High risk cardiopulmonary patients, and a high level of anxiety regarding the procedure, are indications for use of general anesthesia. The routine use of general anesthesia in a majority of ESWL treated patients may result in a slight increase in morbidity compared to routine use of epidural anesthesia.

Renal colic (severe pain) after disintegration of stones may be expected in a majority of patients. Fragments have been measured at less than 2 mm in size in most cases and an uneventful spontaneous passage would likely result. Extracorporeal shock wave lithotripsy treatment resulted in renal colic requiring analgesic therapy in only 16 percent of 945 patients treated in Munich (Chaussy, Schmiedt, Jocham, et al., 1984). The average duration of passing fragments of stones was seven days. The incidence of severe pain has been much higher in the United States, ranging from 50 to 70 percent of patients. Narcotics have been required in the vast majority for control of pain. One possible explanation for this difference may be a result of the increasing willingness to treat larger stones with ESWL and thus cause larger fragments to be discharged after treatment.

Septic hydronephrosis (infection) complicated 3.6 percent of the patients reported by Chaussy's group and these patients were all treated with percutaneous nephrostomy (Chaussy, Schmiedt, Jocham, et al., 1984). Urosepsis was a complication in two (0.4 percent) patients in the Indianapolis experience (McNulty, 1984) and fever was observed in 3 percent of the patients at Stuttgart (Fuchs, Miller, Bub, et al., 1985). Sterilization of infected urinary tracts and use of prophylactic antimicrobials probably contribute to the relatively low rate of serious infectious complications. Extracorporeal shock wave lithotripsy may, however, facilitate infection by causing obstruction of the urinary tract.

Significant non-surgical complications from ESWL have been virtually absent in the reported experience from Germany (Chaussy, Brendel, Schmiedt, 1980; Chaussy, Schmiedt, Jocham, et al., 1982; Chaussy, Schmiedt, Jocham, 1983; Chaussy, Schmiedt, 1983; Chaussy, Schmiedt, Jocham, et al., 1984). The Methodist Hospital (Indianapolis) experience with ESWL complications was described in a letter to the president of the District of Columbia Blue Cross Plan; ESWL had been applied to 479 patients at the time. Significant nonsurgical complications were found in 1.9 percent of patients, including urosepsis, pneumonia, stroke, myocardial infarction, prolonged ileus and pancreatitis. Obstruction requiring a percutaneous nephrostomy occurred in one patient (McNulty, 1984).

Radiation exposure related to the diagnosis, treatment, and followup examinations of urinary tract stones is an area of concern. A comparison of

X-ray examinations for the different therapeutic modalities found the following: for ESWL 14.5 rads, for percutaneous nephrolithotomy 19.5 rads, for open surgery 8.5 rads, and for transurethral procedures 12.5 rads (Fuchs, Miller, Bub, 1985). The amount of radiation exposure associated with ESWL is nearly three hundred times the dose absorbed from a routine chest X-ray. This extent of radiation exposure may be significant especially if there are repeat ESWL sessions (Hendee, 1983). Substitution of ultrasound examinations for plain abdominal radiographs and discarding the post-ESWL intravenous pyelogram can result in a 38 percent reduction in radiation exposure per patient (Fuchs, Miller, Bub, 1985).

The lithotripter produces pulses lasting one microsecond that sound like pistol shots. An adequate sound-proofing environment is needed (Anonymous, 1982).

General contraindications to the safe use of ESWL have been suggested in the literature. These contraindications include patients with cardiac pacemakers or renal artery calcifications, those who are unable to tolerate anesthesia, weigh more than 300 pounds, are less than 52 inches or more than 78 inches tall or have an uncontrolled urinary infection. With current equipment and with the proper precautions, the risks of serious complications associated with ESWL therapy is probably about 2 percent, but may be higher.

The Role of ESWL in the Management of Stone Disease

The extracorporeal shock-wave technique for pulverizing urinary tract stones has already emerged as the preferred treatment among many urologists

(Finlayson, Thomas, 1984; Resnick, 1984). This enthusiasm is based on data showing 80 to 90 percent effectiveness in eliminating stones as a single modality or in conjunction with techniques other than surgery (Chaussy, Schmiedt, Jocham, et al., 1984; Lingeman, Newman, Steele, et al., 1985; Riehle, Fair, Vaughan, 1985; Fuchs, Miller, Bub, et al., 1985). The complete avoidance of a surgical incision and the reported reduced period of convalescence adds to ESWL's attractiveness as a noninvasive treatment of urinary tract stones.

Open surgery for stone disease will likely be used for few patients in the future. Percutaneous nephrostomy with ultrasonic lithotripsy is effective in 95 percent of cases and thus open surgery is avoided. Stones located in the calices, renal pelvis, or upper ureter were best managed by percutaneous ultrasonic lithotripsy until the availability of ESWL. Despite the slight advantage in efficacy of percutaneous ultrasonic lithotripsy over ESWL, the risk of serious complications is substantially greater. Bleeding from trauma to vascular structures occurs in 1 percent of nephrostomy cases (Patterson, Segura, LeRoy, et al., 1985) compared to an approximately 0.6 percent incidence of perirenal hematomas from ESWL (Chaussy, Schmiedt, Jocham, et al., 1984). Thus, ESWL is the preferred treatment for stones in the renal pelvis or calices when there is an indication to remove these.

Stones located in the ureter are more difficult to manage. If a stone is causing sufficient symptoms to warrant an invasive procedure for removal, then ESWL is the preferred therapeutic alternative for those located in the upper ureter. A combination of percutaneous manipulations and ESWL may be expected in a greater proportion of ureteral stones than for stones in the kidney. Extracorporeal shock wave lithotripsy has been somewhat less effective as initial therapy in ureteral stones than it is for stones located in the kidney, but, in combination with percutaneous ultrasonic lithotripsy, over 95 percent of ureteral stones can be removed. The advantages of the noninvasive procedure (ESWL) are lost when a second manipulation such as percutaneous ultrasonic lithotripsy is required.

The United States experience with ESWL offers one encouraging fact--most of the secondary manipulations have been transurethral and not percutaneous. Presumably, the shock waves shatter the stone into fragments small enough to enter the ureter and move sufficiently to be accessible to transurethral manipulations. This approach would limit the risks involved with secondary procedures after ESWL, since transurethral manipulations are considerably safer than are percutaneous procedures. Stones found initially to be in the lower ureter (below the iliac crest) should not be treated with ESWL but approached by transurethral manipulations. Ureteral stones lodged in the same place for more than four to six weeks are not removed effectively by ESWL.

If ESWL becomes widely accepted and applied, then the percutaneous techniques will likely be viewed as a secondary, but complementary, procedure. Percutaneous ultrasonic lithotripsy may be used before or after ESWL; impacted stones may be removed by percutaneous access and use of baskets, forceps, balloon catheters, suction devices and other instruments (Blume, 1983).

The efficacy of ESWL for treating upper urinary tract stones over a three-month followup period has been established. Long term followup, with reports on recurrence rates, has yet to be reported. One major concern is that, in approximately 10 percent of patients treated with ESWL, residual stones are visualized on plain X-rays at three months. These fragments or "stone dust" may act as a nidus for new stone formation and lead to even higher recurrence rates. As a minimum, a recurrence rate similar to the natural history of calcium stone formers is to be expected. Recurrence rates of 40 to 60 percent, however, have been reported after open surgical procedures (Martinez-Pineiro, Gaston de Iriarte, Armero, 1982). Combining medical management and preventive measures with any surgical treatment of stone disease is a necessity.

Extracorporeal shock wave lithotripsy is apparently a relatively safe procedure, although a majority of patients will have painful colic for several days and some morbidity from anesthesia is expected. Morbidity from ESWL compares favorably with open surgery and percutaneous techniques, and mortality is virtually absent. The long term effects of ESWL are in need of study although there are few indications of harmful effects. Although kidney function has been preserved in an unselected subset of patients followed for two years, the possible effect of repeated ESWL treatments also needs to be considered.

The majority of stones to be treated by ESWL will be calcium containing. Besides being the most frequent type of stone (70 to 75 percent) encountered, the radiographic density and size of calcium stones makes ESWL a likely first choice for therapy. Struvite stones should be considered separately since these are usually found in association with recurrent infections with bacteria of the Proteus genus. Many struvite stones grow to enormous size and fill a cast of the caliceal system; these are called staghorn stones. A combination of ESWL, percutaneous ultrasonic lithotripsy and/or open surgery has been proposed as the optimal therapeutic approach for staghorn stones.

Cystine stones are particularly hard and more difficult to fragment with ESWL. One approach reported using chemolysis to disintegrate cystine stones after fragmentation with ESWL (Schmeller, Kersting, Schuller, 1984). Several drugs have been approved by the FDA in the past three years to treat specific types of urinary tract stones. Cellulose sodium phosphate prevents calcium oxylate stone formation by acting as an ion exchange resin and reducing dietary calcium absorption (Marwick, 1983). Acetohydroxamic acid is a bacterial enzyme that helps prevent the formation of stuvite stones but it has only marginal effects on formed stones (Williams, Rodman, Peterson, 1984). Potassium citrate acts by acidifying the urine and correcting low levels of urinary citrate, which normally prevents crystallization of calcium salts. Advances in medical management and prevention of urinary tract stones should be coordinated with surgical treatments in order to minimize recurrence rates. Prevention with dietary changes and/or safe and effective drugs should eventually reduce the need for surgical therapy of stone disease.

The role that ESWL may play in the management of urinary tract stones is illustrated by the experience of the Stuttgart, West Germany Stone Clinic. During the first 11 months after the introduction of an ESWL unit, 1,302 patients were treated and 762 (58.5 percent) received ESWL (Miller, Fuchs, Rassweiler, et al., 1985). Kidney stones were found in 877 patients and

77.5 percent of these were treated with ESWL alone. An additional 19 percent of kidney stone patients were managed with a combination of ESWL and percutaneous nephrolithotomy. ESWL treatment of ureteral stones was limited to those located above the iliac crest and thus ESWL was applied in only 19.3 percent of ureteral stones. A total of 80 patients (6.1 percent) required open surgery. The referral nature of the Stuttgart patients limits the applicability of this experience to the general population of patients with nephrolithiasis. The central role of ESWL in the management of stone disease, however, is borne out by this report. Open surgical procedures for urinary tract stones should be reserved in the future for less than 10 percent of all patients requiring more than conservative medical management.

ESTIMATED DEMAND FOR ESWL

To estimate the number of lithotripters that are needed to serve patients adequately requires deciding on how many patients might (or should) receive ESWL. The demand for a particular treatment, be it ESWL, open surgery, or increased fluid intake, is generally based on what clinicians call "indications." Indications are signs that a clinical condition exists, and, perhaps, that a specific treatment is needed. Of particular importance for an assessment of the demand for ESWL is that, in general, indications for treatment tend to change as new, and often less invasive, technologies are introduced into clinical practice. Because there is a wide range of treatments available for urinary tract stones, and since there have been few comparative studies of alternative treatments for most types and locations of urinary stones, decisions regarding indications for a particular treatment can be a highly individual and sometimes idiosyncratic.

The case of urinary tract stones, the major clinical decision that must be made is whether to wait and see if the stone passes spontaneously or to intervene and remove the stone. In the past, the most common decision has been to allow the stone to pass spontaneously, and perform invasive procedures only if necessary. Specific indications have only been defined for open surgery (perhaps because of the risks involved). The indications for surgery include: 1) infection above the stones; 2) refractory pain; 3) ureteral obstruction; 4) anuria secondary to bilateral obstruction or presence of a single collecting system; and 5) stones that have not passed spontaneously and remain symptomatic after six weeks (O'Flynn, 1983). As less invasive techniques become available, however, it is possible that indications may change toward earlier intervention. In the extreme, the simple presence of a stone in the kidney or upper ureter may be an indication to perform ESWL.

Estimates of the size of the population to whom ESWL might be applied range widely from a relatively small group for whom strict criteria apply, to a much larger group for whom treatment today would normally include only analgesics and high fluid intake, waiting for the stone to pass without intervention. A second issue in estimating the demand for ESWL is to find data that estimate the incidence of urinary stones accurately.

Large population studies of the incidence of urinary tract stones normally use data from hospital discharge records. For example, the

National Center for Health Statistics' Hospital Discharge Survey suggests that there were between 250,000 and 300,000 hospitalizations with a primary diagnosis of urinary tract stones in 1983 (Vital and Health Statistics, 1985). While this may be an accurate estimate of the number of hospitalizations with this primary diagnosis, because of multiple admissions the actual incidence of urinary tract stones in the population may be as little as half of the number of hospitalizations for stones.

Studies of smaller populations suggest that the incidence of urinary tract stones is somewhere between 73.4 and 122 per 100,000 persons per year (Johnson, Wilson, O'Fallon, 1979; Hiatt, Dales, Friedman, et al., 1982). This translates into an incidence of approximately 164,000 to 273,000 urinary stones per year in the United States with sufficient symptoms to require medical attention. It has also been estimated that approximately one-third of stones present initially in the kidney or upper ureter (American Urological Association, 1984). Thus, there may be between 55,000 (164,000 X .33) and 91,000 (273,000 X .33) patients who present with a stone in the upper urinary tract. (Note that, as described earlier, the incidence of urinary tract stones is essentially the same in the populations below 65 years old and 65 years old and above).

It has been estimated by an ad hoc committee of the American Urologic Association that 78 percent of patients with urinary stones have small stones that pass spontaneously with or without the aid of medical management and cystoscopic assistance, that 15 percent of patients have stones that are too large to pass spontaneously, and that the remaining 7 percent have stones complicated by a variety of medical or surgical problems and require open surgical procedures (American Urologic Association, 1984). Thus, four out of five urinary tract stones would be treated conservatively today, with relatively little medical intervention.

If the range of 55,000 to 91,000 potential ESWL patients excludes the 7 percent of patients that have stones complicated by medical or surgical problems, the expected maximum range of possible patients for ESWL is reduced to between 51,000 and 85,000. If one assumes that between one-half and all stones that are small enough to pass spontaneously, and all of the patients who have stones too large to pass spontaneously, are given ESWL, the possible number of patients that might be suitable for ESWL is 26,000 to 85,000 per year. At a rate of 800 procedures per year per lithotripter (an average of three to five per day), the range of possible numbers of lithotripters that are needed in this country to fill the possible demand is between 33 units and 106 units. At a more economically optimal rate of 1,500 stones per lithotripter per year, the number of lithotripters needed ranges between 17 and 57.

Another way to estimate the demand for ESWL is to look at the number of surgical procedures that are currently performed to remove stones in the upper urinary tract. In 1983, there were approximately 12,000 nephrotomies and 53,000 ureterotomies (Vital and Health Statistics, 1985). These two procedures are also used for purposes other than removal of stones, and ureterotomies include removal of stones in the lower urinary tract (to which ESWL would not apply). Thus, it seems reasonable to estimate that of the 65,000 surgical procedures performed in 1983, only perhaps 30,000 to 40,000 would be replaced by ESWL. As described below, this estimate also agrees with other calculations of the possible demand for ESWL.

What are the estimates of the possible demand for ESWL that have been developed by others? The American Urologic Association formed an Ad Hoc Committee to study the safety and clinical effectiveness of the current technology of 1) percutaneous lithotripsy, and 2) noninvasive lithotripsy (ESWL) (American Urologic Association, 1984). In their report to the American Urologic Association, this committee quoted the Dornier Corporation, manufacturer of ESW lithotripters, as having estimated the national "need" in the United States for ESWL to be approximately 33,750 patients. The committee also estimated that there was a range of "need" for ESWL of between 35,000 and 140,000 patients (the latter figure is calculated based on a relatively high incidence rate and the use of ESWL for all patients with upper urinary tract stones, no matter whether the stones would pass spontaneously or not). This committee goes on to estimate that, based on an average of 800 procedures per lithotripter per year, the United States needs between 45 and 175 lithotripters.

Thus, a conservative, though possibly high, estimate of the number of lithotripters needed to meet possible national demand is approximately 75 units. As described in more detail later in this report, the combination of the relatively modest potential demand for the technology and the high costs associated with the provision of ESWL suggests that it is unlikely that this technology will proliferate widely in the way that, for example, computed tomography scanning has. This has many implications for a variety of issues, including access to ESWL, the economic viability of ESWL centers, and the way that physician fees might be calculated for the provision of an ESWL. Future research on urinary tract stones may result in increased prevention of stone formation, which in turn may make ESWL and other techniques for removal of stones relatively less necessary, and newer forms of lithotripsy and other means of removal of urinary tract stones may well supplant ESWL as a treatment of choice.

SECTION II

PAYMENT FOR ESWL

THE INTRODUCTION OF NEW MEDICAL TECHNOLOGIES

New technologies enter medical practice in a variety of ways. Technologies may take years to develop before they become part of accepted clinical practice. Whether they are new drugs or new types of equipment, many medical technologies that have been introduced into practice in recent years have developed from basic science research, often in fields that were far removed from medical care. Technologies such as gene-splicing, fiberoptics, computer enhancement of radiologic images, and magnetic resonance imaging all developed from basic science research that was often undertaken with little expectation that the techniques being developed would have application in the care of patients.

Once new scientific and technologic knowledge is applied to creating drugs and equipment for the care of patients, clinical research studies are generally undertaken to assess the safety and efficacy of the new medical technology. The process by which new drugs become approved by the Food and Drug Administration for general use in patient care is perhaps the most rigorous testing of the safety and efficacy of medical technologies. New medical equipment, on the other hand, often undergoes only safety testing and confirmation of technical capability, with little information available initially about efficacy.

In general, medical technologies are introduced into practice well before studies have been undertaken of their potential impact on the care of patients, such as whether they substitute for other technologies or are additive in the patient care process, or whether their broader social costs are balanced by the social benefits that will accrue by their use. As described below, often payers for medical care are put in the position of having to decide on whether a service is no longer "experimental," and thus can be paid for, well before broader questions relating to efficacy and cost-effectiveness have been dealt with adequately.

There are a variety of decision-makers in the process of the development, introduction, and use of new medical technologies. Researchers who undertake the basic science studies that are used in the early development of medical technologies, and their sources of funding (primarily the National Institutes of Health), exert an extremely important, yet often unrecognized, influence on the development of new technologies. With ESWL being, perhaps, the best example, new technologies are also sometimes developed by individual companies that apply methods and knowledge that have been gained from work in other areas to the development of a medical technology. Of particular importance to note is that basic researchers, and their funders, and companies in fields often unrelated to medical care, have an large influence on the eventual introduction of technologies; these individuals and institutions, however, are rarely brought into discussions after the introduction of a technology concerning whether the technology in question is worthwhile from a broader social perspective.

Once a technology becomes available, and has been shown by (a few) clinicians to be at least somewhat efficacious, other clinicians and payers for medical care are often put in the position of needing to provide and pay for the new technology. For example, many new surgical procedures are asked for by patients, provided by physicians and paid for by insurance well before the surgery has been compared formally to alternative services. Patients become influential in this decision-making process, particularly as the media publicizes the benefits of a new technology, often with an inadequate description of the problems associated with the technology in question. In general, once a medical technology has been introduced, and its safety and efficacy have been judged to be minimally adequate, it may be very difficult for clinicians who doubt its relative efficacy to withhold provision of the technology, for payers to withhold payment for the technology, and for patients to understand why a particular technology that they have just read about in the newspaper is being denied to them. Thus, it becomes almost inevitable that many new medical technologies are introduced and used widely, well before large-scale clinical and economic studies of them have been undertaken.

PHYSICIAN PAYMENT FOR ESWL

Decisions by Payers Regarding New Medical Technologies

Medicare physician payment is administered by health insurers who contract with Medicare to be the Medicare Part 3 "carrier" (Part A refers to hospital payment). Although the general characteristics of Medicare physician payment are stipulated in law, decisions about what new services to pay for, and how much to pay, are usually left to the carrier. In contrast to the totally federally funded Medicare program, Medicaid programs are at the discretion of individual states, where funding is shared with the federal government. Most states contract with a "fiscal intermediary" (often a health insurer) to pay physicians, with payment most often based on fee schedules (Showstack, Blumberg, Schwartz, et al., 1979). Again, however, coverage decisions are generally left to the fiscal intermediary.

Medicare carriers, Medicaid fiscal intermediaries, and other third-party payers for medical care have two basic decisions to make concerning payment for new medical technologies. First, most third-parties will not pay for a procedure that is considered to be "experimental." Thus, the first decision that most third-parties must make is whether a procedure has passed from the experimental stage to a stage where it may be used clinically. Once a service or procedure has been judged to be no longer experimental, the payer must then decide on how much it is willing to pay the provider and/or the patient for the procedure. For many health insurers, including in particular Medicare, once physicians begin billing for a service the claims submitted are used to determine the "community rate" for the service. This community rate then often supercedes the initial rate determined for the new technology.

The decision concerning whether a procedure is experimental, or has ceased to be experimental and is now part of accepted clinical practice, is made in a variety of ways by third-parties. Each payer determines its own methods for answering this question. These methods range from relatively formal committees that are convened periodically to decide on whether new procedures might be paid for, to decisions by individual administrators of the third-party, sometimes in consultation with others.

The process used by Blue Shield of California illustrates a relatively formal decision-making mechanism. Approximately four times a year the Medical Policy Committee of Blue Shield of California is convened to discuss, take testimony about, and decide upon the acceptability of new medical procedures and services. This committee is composed of primarily clinicians, but others, such as economists, are also included. Attending, and often testifying at, the public meetings of the committee are persons interested in the development and use of the new technology. The committee assesses the information that is provided to it by the staff of Blue Shield of California, the testimony that is presented to the committee, and their own knowledge of the clinical, ethical, economic, or other issues surrounding the use of the technology, and then votes on whether the technology is still experimental or is part of current acceptable clinical practice. Occasionally the committee also suggests guidelines about the amount of payment for a particular technology, but this is somewhat unusual.

Once the Medical Policy Committee of Blue Shield of California has decided that a technology may be paid for, medical consultants are asked to provide a judgment about the worth of the technology. These consultants are usually clinicians who are specialists in the clinicial area that the technology is primarily used in. They are asked to compare the new technology to another procedure or service that is performed in that specialty, one that has similar clinical uses, and to assess the skill, knowledge, and difficulty involved in the provision of the new technology. Once this "comparable" procedure is decided upon, a third-party has the means by which to judge the bills that are received from physicians and patients.

Most third-parties, however, use a much less formal method to decide whether, and how much, a physician should be reimbursed for a new procedure. Often payers will not convene a formal committee to make the decision concerning the acceptabiity of the procedure but will rather consult directly with specialists in the appropriate field to ask their opinion of whether the procedure is beyond the experimental stage, and of the approximate worth of the procedure. Judgments by many third-parties are often based mainly on what major insurers such as Blue Cross/Blue Shield and Medicare carriers decide about the acceptability and payment level for a particular procedure. Many smaller third-parties do not have either the administrative resources or enough claims experience to make judgments on their own about new technologies; thus, smaller payers for medical care (as well as some of the larger private insurers) find it much easier to follow the path of major insurers than to have to make the decisions on their own.

Groups such as the Health Insurance Association of America provide information to members about other insurers' judgments concerning the acceptability of new procedures and services.

Critical Issues in Payment Decisions

There are, in general, no laws or regulations concerning how a payer for medical care must decide about the inclusion of new procedures and services in their health insurance policies. For most health insurers, one, or just a few, individuals make decisions about payment, and often these third-parties follow the lead of others, as described above. Several critical issues are apparent in this process. First, even when a committee of "nonpartisan" individuals is brought together to decide on the clinical acceptability of a new procedure, there is no guarantee that broader questions will be considered, such as the impact of the new technology on the organization and delivery of medical care, the social and economic costs of the new technology, and other trade-offs that may be implicit in the inclusion of a new procedure in the third-party payer's benefit package. Second, whatever the normal means by which insurance companies decide on payment levels, whether they are based on usual, customary, and reasonable payment, or on fee schedules (Showstack, Blumberg, Schwartz, et al., 1979), the "price" of a new technology is often determined by a few physicians who initially provide the service or procedure (Delbanco, Meyers, Segal, 1979).

In the case of ESWL, for example, even with enough lithotriptors operating to provide services to the entire population of the United States, there may be only several hundred physicians charging for the performance of the procedure. When a third-party payer decides on the level of payment for a procedure it must also take into consideration the number of physicians who are providing the procedure, and what the availability and accessibility of the procedure would be should the payer decide to pay less than the "going rate" in the local community.

Finally, the choice of from whom to seek advice regarding the clinical acceptability and payment level for a new technology is critical in the process used by third-parties to decide on payment for a new technology. As described above, most third-parties seek advice from a physician from a specialty to which a new technology is judged to belong. In the case of many new technologies, services could be provided by a variety of types of physicians. In their payment to physicians, third-party payers rarely refuse payment because a physician is not "qualified" to perform a particular service or procedure. Generally, these decisions are left to other mechanisms such as the licensing system and hospital decisions regarding admission privileges. The choice of a particular specialist (e.g., a urologist) to decide on the comparability of a procedure (e.g., ESWL) to other (urologic) procedures makes an implicit decision about the economic worth of the new procedure (e.g., that ESWL is a surgical procedure, even though no "surgery" is performed).

Current Payment for ESWL

Physicians are now reimbursed routinely for ESWL by third-party payers. The methods used by each payer to decide on payment levels varies greatly, and it is not always possible to ascertain the exact amount paid. (The following information was collected in interviews with persons in positions of responsibility in the Blue Shield plans of several states that have lithotriptors.)

In Massachusetts, an interspecialty Medical Advisory Committee meets monthly, but, to speed the decision-making process, this committee was not formally consulted when Blue Shield agreed to reimburse physicians for ESWL. The decision was based on expert opinion, the "general public demand," and the perception that ESWL was a "finished product" no longer in an experimental stage. The payment rate for ESWL was set at approximately $1250, the rate for pyelolithotomy plus urography.

Blue Shield of Greater New York considered ESWL experimental until after FDA approval, when it became a covered benefit. In New York, the usual fee for pyelolithotomy is approximately $1,900; it was expected by the persons who were interviewed at Blue Shield of Greater New York that the actual, negotiated fee for ESWL will be substantially less.

Blue Cross/Blue Shield of Texas was reported to have considered ESWL a routine "surgical" procedure and decided upon a level of reimbursement based on a surgeon's time involved in monitoring the procedure. Reimbursement has been set at a rate "somewhat less than $2000."

Blue Cross/Blue Shield of Virginia has reimbursed physicians for ESWL since October, 1984, after consultation with outside urology experts. Negotiations with the one urologist-owned facility that performs ESWL resulted in an agreement to reimburse physicians at approximately $1,200, about the same level as a percutaneous removal of a stone in the upper ureter. Apparently, the rate was determined by comparing ESWL to other procedures of "comparable worth."

Indiana has reimbursed physicians for ESWL since February 1, 1985, while on May 22, 1985 Blue Shield of California's Medical Policy Committee decided that ESWL was no longer an experimental procedure and thus could be reimbursed. Most other major insurers have elected to reimburse ESWL at a rate similar to that paid for a surgical procedure that ESWL replaces. The incentive for the carrier to offer a lower fee has been tempered by the need to maintain a non-adversarial relationship with both patients and physicians.

Payment for Other Urologic Procedures

In the early use of ESWL, many urologists have argued that they should be paid for the procedure at approximately the same rate that they would be paid for a nephrolithotomy. Shown in Table 2 are charges for nephrolithotomies and other stone-related procedures that were billed to Medicare in California in 1983. As can be seen, nephrolithotomy had a median charge of $1,610, as did pyelotomy, with ureterolithotomy having a slightly lower median charge of $1,495. These charges are for "surgical" procedures, that is, they include, in addition to the actual procedure, a preprocedure visit to the physician and all subsequent necessary follow-up care for a specific number of days. In the case of nephrolithotomy, for example, the physician charge of approximately $1,610 includes seeing the patient in his or her office before the procedure, for performing the procedure, and for visiting the patient in the hospital and as an outpatient

Table 2

Charges Billed to Medicare for Selected Stone-Related Physician Services* in California, 1983

1969 CRVS** Code	Description	Median Charge
Incision		
50060	Nephrolithotomy; removal of calculus	$1,610
50130	Pyelotomy; with removal of calculus (pyelolithotomy, pelviolithotomy)	1,610
50620	Ureterolithotomy; middle one-third of ureter	1,495
Transurethral		
52320	Cystourethroscopy; with removal of ureteral calculus	600
52800	Litholapaxy, crushing of calculus in bladder and removal of fragments; simple, small (<2.5 cm)	783
52805	Complications or large (>2.5 cm)	1,120

* Professional fees only, excludes technical component

** California Relative Value Studies

Source: Blue Shield of California

for 90 days after the procedure. As also can be seen in Table 2, the transurethral procedures, such as cystourethroscopy (median charges $600), have charges that are substantially less than the procedures requiring an incision.

An obvious question becomes, how can one justify charging as much for a noninvasive procedure, such as ESWL, as would be charged for a surgical procedure, such as nephrolithotomy? In the next sections, the physician component of the ESWL procedure is described and two different models for estimating physician payment for ESWL are discussed.

A Hypothetical Episode-of-Illness Model for the Payment of Physician Fees for ESWL

One way to derive a level of payment for ESWL is to assess what the total charges would be for the individual services performed in the process of providing a ESWL. In general, surgeons are reimbursed a single amount for a procedure, including both preprocedure and postprocedure visits with the patient, whether or not the procedure is "uncomplicated" or "complicated". Thus, the amount that a surgeon is paid for a procedure is likely to be an average of uncomplicated and complicated cases. Table 3 shows a hypothetical model of charges by a urologist for ESWL for services performed for both an uncomplicated case and a complicated case. (Note that either an anesthesiologist's or nurse anesthetist's fee would be added to these figures. Their fees, of approximately $200 to $400, are essentially a "fixed" cost, so they have been omitted from this discussion.)

In a prototypical uncomplicated case, there is one prehospital visit to the physician, a hospital visit that includes a history and physical exam, the procedure itself in the hospital, two subsequent hospital visits to the patient after the procedure, and, finally, two office visits by the patient subsequent to discharge from the hospital. The prototypical complicated case also includes one preprocedure exam in the physician's office, a history and physical in the hospital, the performance of the procedure, but, in this case, there would be five visits in the hospital to the patient subsequent to the procedure, and four outpatient visits. The fees in Table 3 are calculated based on the 1985 fee schedule used by California Worker's Compensation for each listed procedure. Also listed is the procedure's

Table 3

Physician Payment Models for ESWL Based on Estimated Number of Visits at Current Payment Levels

	CRVS Code*	Fee**	Uncomplicated Case Number of Visits	Uncomplicated Case Total Charge	Complicated Case Number of Visits	Complicated Case Total Charge
Prehospital						
Comprehensive Exam	90070	$ 50	1	$ 50	1	$ 50
Inhospital						
History and Physical	90220	$108	1	$108	1	$108
(Procedure - 90 minutes)***	--	$204	1	$204	1	$204
Limited Exam	90250	$ 30	2	$ 60	2	$ 60
Intermediate Exam	90260	$ 38	0	$ 0	3	$114
Posthospital						
Limited Exam	90250	$ 30	2	$ 60	2	$ 60
Intermediate Exam	90260	$ 38	0	$ 0	1	$ 38
			TOTAL	$482		$634

* 1974 California Relative Value Studies code

** Amount paid by California Workers Compensation in 1985

*** Procedure cost estimated based on average compensation per hour ($218,750/1610 hours, see Table 4 and Appendix)

California Relative Value Studies code number. Because charges for "surgical" procedures are not normally separated from office visits, we have estimated that the procedure itself would include a charge of $136, which is based on assumptions that are described in the next section, below. (If another type of procedure is performed in conjunction with the provision of ESWL there would be an additional charge.)

Experience so far with ESWL suggests that there are relatively few "complicated" procedures. Thus, using the logic of this model, the appropriate physician charge for ESWL might be, perhaps, only slightly more than the fee of $482 that is shown in Table 3 for an uncomplicated case. Even the hypothetical charge for a "complicated" case is far below the actual fee for a more invasive procedure (Table 2).

An "Efficient" Financial Model of Professional Costs

Another way to estimate physician reimbursement for ESWL is to calculate its theoretical costs of production. It is perhaps easiest to understand this model if one thinks of it as a prepaid group practice calculating the number of procedures that could be completed by a urologist who is hired full-time to perform ESWL, including preprocedure and postprocedure visits. The details of the model are shown in Table 4.

It is assumed in this model that a physician provides patient care 35 hours per week for 46 weeks per year, totalling 1,610 patient care hours per year. Similar to the model described above, this model includes both uncomplicated and complicated cases. In contrast to the model described above, however, this model is concerned primarily with the amount of time

Table 4

"Efficient" Financial Models of Professional Costs for ESWL

VOLUME

Patient Care = 1610 hours per year

46 weeks per year (6 weeks vacation)

35 hours per week (5+ hours per week for continuing education, etc.)

Time devoted to office visits, procedure, writing notes, etc.

	Uncomplicated Case	Complicated Case
Outpatient		
Prehospital history and physical exam	N=1 = 1 hour	N=1 = 1 hour
Posthospital follow-up visits	N=1 =0.5 hour	N=2 = 1 hour
Inpatient		
Procedure	N=1 =1.5 hours	N=1 1.5 hours
Follow-up Visits	N=3 =1.5 hours	N=6 3 hours
Total	4.5 hours	6.5 hours

Number of Procedures per Year

Uncomplicated Case: 1610 hours ÷ 4.5 hours = 358 procedures

Complicated Case: 1610 hours ÷ 6.5 hours = 248 procedures

EXPENSES

One FTE Urologist, per year	$175,000
Fringe benefits (25 percent of salary)	43,750
Total	$218,750

COST PER PROCEDURE

Uncomplicated Case: ($218,750 + 358) = $611

Complicated Case: ($218,750 ÷ 248) = $882

Note: These models assume that a referring physician would transfer total responsibility for the patient or would perform the procedure and all follow-up visits himself. There may also be additional costs for an anesthesiologist or nurse anesthetist, and a radiologist. Malpractice insurance fees are assumed not to change for a urologist as a result of performing ESWL; these fees are therefore omitted from the model.

devoted to each of the activities that are described in Table 3. The estimates of time in this model include routine tasks, such as writing notes.

It is assumed that the patient is hospitalized. The total amount of time required for "history and physical" is 60 minutes, a "comprehensive" exam is 40 minutes, an "intermediate" exam is 30 minutes, a limited exam is 20 minutes, and the procedure takes 90 minutes. Using the number of services estimated in the previous model, the total amount of professional time calculated in this model to take care of an uncomplicated case is 4.5 hours and of a complicated case is 6.5 hours. Thus, it is estimated that if all cases are uncomplicated, approximately 358 procedures per year could be performed by the urologist, while if all cases were complicated, approximately 248 procedures per year could be performed.

This model assumes that the cost to the group practice of hiring a full-time urologist to perform procedures is $175,000 per year salary, plus $43,750 in fringe benefits, for a total cost of $218,750. (Note that this figure is based on a "surgeon's" hourly rate, which is based on the pro-technology bias in our reimbursement system [Showstack, Schroeder, Steinberg, 1981].[See appendix.]) Dividing $218,750 by the number of procedures per year implies that the actual cost to a group practice to hire a urologist (at current fee-for-service income levels) to perform ESWL full-time is approximately $611 for an uncomplicated case and $882 for a complicated case. Again, assuming that most cases are uncomplicated, the typical cost per case might be closer to approximately $550.

It is conceivable, for example, that an organization or a group of organizations that have a volume of stone disease approaching 1,200 cases per year might purchase their own lithotripter and hire 3 to 4 urologists to to care for ESWL patients. In this case, the average professional cost per ESWL treatment would be approximately $650, approximately one-half the fee that the group practice would have to pay if a urologist were paid the same rate as urologists currently charge for a lithotomy.

HOSPITAL PAYMENT AND ESWL

Extracorporeal shock wave lithotripsy has been performed in the past primarily as a hospital procedure. The patient is hospitalized, undergoes the procedure, and stays in the hospital for several days for observation. In the future, however, ESWL may become an outpatient procedure, with hospitalization occurring only for patients whose symptoms, such as pain and gross hematuria, require them to be observed closely for several days. The fact that ESWL may be performed in an ambulatory setting adjacent to a hospital raises several issues regarding the payment for the procedure. Under Medicare diagnosis-related groups (DRG) payment, the technical fee for an ESWL performed on a "hospitalized" patient, that is, one who is hospitalized the day of the procedure, is included in DRG payment. On the other hand, if the patient is not hospitalized, then the physician and technical fees for ESWL would be paid by Medicare Part B.

Although Medicare has decided to pay for ESWL when it is performed on a hospitalized patient in DRGs 323 or 324, to illustrate the choice presented to Medicare, the following data from the Medpar database are provided. The Medpar database consists of a 20 percent sample of all Medicare admissions during 1981. It was the original source for developing and verifying the DRG methods currently used by Medicare to pay hospitals. Table 5 shows the DRGs, and their definitions, that could be used for patients who are hospitalized for, or subsequent to, ESWL. Table 6 shows data derived from the Medpar database for admissions in 1981 in DRGs relating to stone disease.

Table 5

Definitions of DRGs Related to Urinary Stone Disease

DRG	Definition
304	Operative procedure on kidney, ureter or major bladder for non-malignancy, age >69 and/or complications and/or co-morbid conditions
305	Operative procedure - kidney, ureter or major bladder, non-malignancy age < 70 without complications or co-morbid conditions
310	Transuretheral procedures, age >69 and/or complications and/or co-morbid conditions
311	Transuretheral procedures, age >70 without complications and/or co-morbid conditions
323	Medical - urinary stones, age >69 and/or complications and/or co-morbid conditions
324	Medical - urinary stone, age <70 without complications and/or co-morbid conditions
325	Kidney and urinary tract signs and symptoms, age >69 and/or co-morbid conditions
326	Kidney and urinary tract signs and symptoms, ages 18-69 without complications and/or co-morbid conditions.
327	Kidney and urinary tract signs and symptoms, ages 0-17.

Table 6

Medicare Admissions in DRGs Relating to Stone Disease, 1981 (20 percent sample)

	DRG	N (%)	Mean Hospital Charge (Dollars)	DRG Weight	Mean Length of Stay	Outlier Limit (Days)
Surgery	304	1,725 (16)	5,077	1.7952	12.8	33
	305	1,039 (9)	3,708	1.7043	11.9	32
	310	6,162 (58)	1,534	0.7071	4.9	20
	311	1,779 (17)	1,277	0.5871	4.1	18
TOTAL		10,705 (100)				
Medical	323	6,691 (64)	1,551	0.7131	4.9	25
	324	3,165 (36)	1,180	0.5472	3.9	19
TOTAL		8,856 (100)				
Post-Stone	325	6,799	1,577	0.7247	5.4	25
	326	2,020	1,274	0.5875	4.3	21
	327	0*	0*	0.5027**	3.1**	14**

* Age 0-17 not included in Medpar database

** Medicare data supplemented by data from Maryland and Michigan

Source: Medpar database, Health Care Financing Administration

The surgical DRGs (304, 305, 310, 311) are relatively broadly defined and may include a number of cases beyond those that would ultimately receive ESWL. This is because these DRGs encompass other major ureter and kidney procedures as well as surgery for stones. Estimates derived from these data should, however, represent the upper limit of stone surgery.

DRGs 304 and 305 include major open surgery on the kidney. There were 1,725 cases in DRG 304 (kidney, ureter surgery, age greater than 69 and/or complications and/or co-morbid conditions). DRG 305 is the same DRG as 304 for patients less than 69 years old without complications or co-morbid conditions. Together they accounted for 25 percent of all surgery performed on the kidney. It is this group of patients who would be most affected by the use of lithotripsy. The second major group of patients who received surgery in 1981 were those who underwent a transuretheral procedure. DRGs 310 and 311 accounted for 75 percent of the cases that may have undergone a "surgical" procedure for stone removal. It can be inferred that a large proportion of patients in DRGs 310 and 311 received procedures for removal of stones and, again, there would be fewer of these procedures because of the use of ESWL. Some patients who undergo ESWL may need a transuretheral procedure to remove small fragments that do not pass spontaneously. Therefore, the expected reduction in transuretheral procedures may not be as great as the reduction in open procedures.

Medicare currently pays for ESWL as an inpatient procedure in DRGs 323 and 324, which are for the medical treatment of stones. Presumably this includes patients who are admitted for supportive (fluid and analgesic) therapy while the stone is passed spontaneously. It may also include metabolic work-ups for stone disease. There were almost as many of these admissions in 1981 for the Medicare sample (8,856) as there were total surgeries in DRG 304, 305, 310, and 311 (10,705). As currently used, ESWL has no role in the acute care of patients with stones; it is unclear how this large pool of stone disease will be affected by ESWL. It can be argued that as ESWL becomes more common, the criteria for its use in the acute phase of stone disease will be less restrictive, and many of these patients may receive ESWL. Thus, there would be a shift from medical treatment to surgical treatment.

Finally, there is a group of patients, as large as the medical treatment group, who are now categorized in DRGs 325, 326 and 327. These DRGs include signs and symptoms of kidney disease without surgery or stones. If ESWL were to be performed in the outpatient setting, and if the patient then needed to be admitted for post-ESWL symptoms related to medical problems (hematuria, infection, pain), then these DRGs might be used.

ESWL AND MARKET FORCES

In many ways, the economics of ESWL are unique. The most important economic characteristics of ESWL are that, at least for a time, a single commercial company controls the distribution and placement of lithotripters; and, there is a theoretical limit to the national need for ESWL for urinary tract stones, which is likely to be accommodated by fewer than 100 units. In addition, once ESWL becomes available in an area, it will probably become the standard of care, replacing more invasive procedures. These factors, plus ESWL's relatively high acquisition costs, suggest that there will not be wide proliferation of lithotripters. Finally, movement away from retrospective payment for medical care to prospective payment creates a situation where new technologies may not be able to automatically recover their fixed and variable costs.

An illustration of this dilemma might be the introduction and use of ESWL for a population such as that of the greater San Francisco Bay Area. The Bay Area has a population of approximately five million persons, which implies that there are between 1,000 and 2,800 patients per year for whom ESWL may be the procedure of choice (for the sake of argument, this discussion ignores populations that are beyond approximately 50 miles of the greater Bay Area). Thus, it appears that two to three lithotripters would be adequate to serve the population in the Bay Area (at between 500 and 1,200 procedures per year per lithotripter).

With two lithotripters active, each would be used for approximately 850 to 1,500 patients per year. This volume implies a cost for the technical component of each procedure of approximately $900 to $1,500 (AHA). How would patients, physicians, and payers react to this situation? Presumably, both patients and physicians would regard ESWL as the treatment of choice, and would wish to establish referral relationships with ESWL centers. Some patients might be as far away as 40 miles from the closest lithotripter; thus, there might be some minor inconvenience to patients caused by travel to the lithotripter.

Urologists, on the other hand, would be presented with a new and challenging situation. Today, the provision of ESWL to most patients is limited to urologists attached to the units themselves. If community urologists refer their patients to an ESWL facility for care, it seems likely that responsibility for many patients will be transferred to the urologists associated with the ESWL center. In addition, because of the small number of units in the area, community urologists would have relatively limited bargaining power. This, in turn, implies that some urologists might choose to wait for small stones to pass spontaneously. They might also perform invasive procedures themselves rather than refer their patients to the ESWL center and lose both responsibility for the patient and payment for performing a procedure. (Several ESWL centers have reported to the investigators that community urologists are referring fewer patients than expected.) Finally, as has happened in the San Francisco Bay Area, community urologists and other physicians may become part-owners of the lithotripter. In this situation they may be somewhat more likely to refer patients to the ESWL center.

Payers are also put in a difficult bargaining position by the presence of only two lithotripters in the area. The Kaiser Permanente Health Plan, for example, has apparently decided that its volume of stone surgery is not high enough to justify the acquisition of its own lithotripter, and, therefore, it will negotiate with the available ESWL facilities to care for Kaiser patients. With only two lithotripters in the area, payers for health care and prepaid group practices, such as Kaiser, would have to purchase services from a virtual monopoly.

What if, on the other hand, there were four or more lithotripters in the San Francisco Bay Area? A variety of factors would change, some quite dramatically, although not necessarily for the better. Of primary concern, perhaps, is that the volume of services performed at each site would be reduced to perhaps from 200 to 700 procedures per year. Because of the relatively high fixed costs of ESWL, this low volume would raise the technical costs for the procedure quite dramatically, from approximately $1,500 per case for 800 ESWL treatments per year to perhaps as much as $5,000 per case for 250 per year. This would, undoubtedly, create a very unstable marketplace; payers might contract with the less expensive centers rather than the the low volume/high cost facility, possibly leading to the latter's eventual bankruptcy.

As with all medical procedures, there is also a question of whether the team that is providing ESWL at a low volume facility can maintain competence while only performing approximately one ESWL per day. On the other hand, with four lithotripters operating, patients would likely be able to travel to a closer lithotripter, and there might be enough competition among the ESWL facilities to allow individual community urologists to establish agreements that would assure that patients would be transferred back to their care, possibly even while the patient is still in the hospital following a procedure. Finally, payers, such as health insurers and groups such as Kaiser, would have more market-power in the sense that they could account for a higher proportion of the annual number of procedures performed at any one center. Again, however, the high fixed costs of ESWL suggest that few low volume centers would be able to survive in a competitive environment.

(One might argue that the costs of ESWL could be spread over the charges for other services in a hospital or ambulatory care center, thus "cross-subsidizing" the lithotripter. In recent years, however, the trend has been away from cross-subsidization, with charges set much closer to actual costs than in the past. This movement toward more accurate cost accounting has been strengthened by competition in the health care marketplace. It seems highly unlikely today that a hospital would tolerate large losses in its ESWL facility, especially if the hosital were unable (because of competition) to raise charges elsewhere.)

The availability of a technology sometimes has the effect of changing the criteria for treatment of a particular condition. In the case of ESWL, most centers are currently planning to use the procedure only on a scheduled, nonemergency, basis. What if a situation developed where there was such low volume use of a particular lithotripter that emergency procedures could be performed? While this is a possibility, it does not seem very likely. Even today very few invasive procedures for the removal of kidney and ureter stones are done on an emergency basis. In general, patients admitted with severe symptoms, such as pain and hematuria, are provided with treatment that is aimed primarily at symptom relief, with any stone removal procedures occurring at a later date. Since it is possible to relieve the acute symptoms of kidney and ureteral stones, it appears that it would be preferable clinically to continue to do so and to schedule ESWL once the acute symptoms have subsided.

Is it possible that the criteria for the use of ESWL might be expanded to include many more patients? If all patients with kidney and upper ureteral stones were to be provided with ESWL, even those with stones that might pass spontaneously, this would, at most, double the need for lithotripters. Given these expanded criteria, there would still be a need in the United States for only approximately 75 to 100 lithotripters, depending on volume of use. Thus, criteria for use could be expanded greatly, yet it would not affect the basic economics of ESWL that suggest a limited market that would become rapidly unstable with the proliferation of lithotripters.

Extracorporeal shock wave lithotripsy presents an interesting economic dilemma. In theory, it is preferable to have a great enough availability of a particular technology to establish a relatively competitive marketplace for its use. In the case of new technologies that have both high costs and relatively few patients in need of them, such as ESWL, the proliferation of centers that are providing the technology may create a marketplace where the additional lithotripters that are producing the "competitive" situation may not be economically viable.

MEDICARE PHYSICIAN PAYMENT

Proposed Medicare Payment Methods

When Medicare was enacted, the method of physician reimbursement to be used became part of the Medicare law. This method was, and still is, based on usual, customary, and reasonable (UCR) fees (in Medicare terminology called customary, prevailing, and reasonable [CPR]). The usual, customary, and reasonable method of determining payment levels was relatively new, and not commonly used, prior to Medicare (Showstack, Blumberg, Schwartz, et al., 1979).

Briefly, UCR assumes that there is an economic market for physician services and that payment by Medicare to physicians should be based on this market for services. Reimbursement levels are calculated based on the amounts charged in a previous time period for a particular service by both an individual physician and other similar physicians. If enough data are available to a health insurer, payment levels may be differentiated according to the specialty of the physician and the geographic area in which the physician practices. Because of Medicare's mandate to pay physicians based on UCR, many insurers have adopted UCR-like systems for paying physicians.

Among the many problems created by the UCR method of setting payment levels is the tendency for fees, and thus payment, to continue to rise in a relatively unlimited fashion, because tomorrow's payment is based on today's charges. This general inflation in physician fees has caused a re-evaluation of the use of UCR by Medicare, and several other methods of payment have been proposed as alternatives (for a more complete discussion of fee-for-service physician payment, see Showstack, Blumberg, Schwartz, et al., 1979).

There are four basic methods that are being discussed as possible alternatives to the current Medicare physician payment system, as well as a number of possible variants of the four. The first method is modification of the UCR system, in which, perhaps, specialty and geographic differentials would be eliminated. A second method being considered is to change from UCR to a fee schedule, where the amount Medicare would pay for a particular service would be determined by a scheduled fee rather than by the community rate of payment. These individual fees would have to be determined in some way, possibly by negotiation between Medicare and one or more physician groups. Fee schedules are commonly used by Medicaid programs and by a variety of commercial health insurers, although the latter group has generally moved toward UCR payment in recent years. A third alternative would be to "package" services, based on either a diagnosis, such as in DRG hospital payment, or based on an episode of illness. For a service such as ESWL, for example, it might be possible to package the professional fee and technical fee components of the provision of the service with the additional charges that would accrue due to any hospitalization, such as for per diem and ancillary services. Finally, Medicare might move toward a completely capitated system in which it would pay a health maintenance organization, preferred provider organization, or other group, a set amount per month for the relatively complete care of a Medicare beneficiary. Combinations of these four options are available, as are alternatives within each option. Below we discuss each of these options in the context of the clinical use and economics of ESWL, and the effect that each option might have on the use of, and expenditures for, ESWL by Medicare beneficiaries.

Generic Issues

Changes in the way that Medicare pays physicians will affect a variety of issues, but of most concern are the potential effects on quality, access, and costs. While quality may be defined in a variety of ways, in the context of this discussion quality care for Medicare beneficiaries refers to care that meets minimum community standards for the general population. Implicit in this definition is the concept that care received by the elderly will be of similar quality to that provided to the population below 65 years old who have standard health insurance. Access is the ability to receive quality care. For purposes of this discussion, cost refers to monetary costs to the federal government and to the individual patient.

Implicit to the discussion that follows of the effects on quality, access, and costs of potential changes in Medicare physician payment are several characteristics of ESWL that have been discussed above. Foremost among these characteristics is the probability that ESWL will soon become the standard of care in many communities for removing upper urinary tract stones. Thus, by definition, access to ESWL will be an essential part of quality care for urinary tract stone disease. Second, the likely limited number of ESWL centers implies that a major concern will be the burden placed on the elderly of travel to a facility that may be hundreds of miles away. Access to ESWL will also be affected by the out-of-pocket costs incurred by Medicare beneficiaries; these costs will be determined, in large part, by the method of payment chosen by Medicare.

There are also other questions surrounding the use of ESWL that affect an analysis of different physician payment mechanisms. These questions include the long term clinical efficacy of ESWL, and the willingness of community urologists to refer patients to ESWL centers. Finally, the high cost of ESWL and the relatively limited number of potential patients with upper urinary tract stones makes ESWL a likely candidate for payors for medical care to attempt to negotiate directly with providers to guarantee access and to fix costs-per-case. For providers, negotiated agreements will mean increased utilization of their ESWL facility, the ability to cover costs, and possibly even the survival of their facility in a competitive marketplace. Medicare already has established a precedent in negotiating with providers of renal dialysis to care for patients who have end stage renal disease; the extension of this precedent to ESWL may be a logical next step.

Professional and Technical Fees

Charges for the provision of a technological service may include several different types of fees. The physician will be paid based on the "professional component" of the service. There may also be charges for the "technical component" of the service, and there may be additional charges for any hospitalization that occurs. The professional component of the service pays for the physician's participation (expertise, time, etc.), while the technical component pays for the costs of the equipment and supplies.

Medicare Part A pays a prospectively set amount for hospital services based on the patient's diagnosis. If ESWL is performed as an inpatient procedure, the technical component will be part of the Medicare DRG payment (in either DRG 323 or DRG 324). (The choice of a "medical," as opposed to a "surgical," DRG for ESWL is apparently based on the noninvasive nature of the procedure.) Payment to a hospital based on these DRGs may be substantially less than the costs of the procedure and subsequent hospital stay. Medicare Part B pays for physician services, including the technical fee if the procedure is performed in an ambulatory setting. Decisions have to be made by Medicare Part B carriers about the amount of payment for professional services and for the technical component. In the case of ESWL, the professional component is generally billed by a urologist, and possibly an anesthesiologist, while the technical component may be billed separately by the ambulatory facility or, as described above, included in DRG payment.

Usual, Customary, and Reasonable Payment

The basic method of setting levels of payment by Medicare carriers for medical services is UCR. As new technological procedures are introduced into practice, payment rates are set by the Medicare carrier after the procedure has been judged to be no longer experimental. These early payment levels, however, eventually give way to payment based on UCR, which uses the claims for reimbursement received from physicians by Medicare carriers to calculate payment. (This is not to say that the early payment levels have no effect on subsequent payment, since they may have a large influence on the level of fees charged by physicians in an area.)

The basic idea behind UCR is to allow the medical marketplace to determine the appropriate level of payment for a service. For UCR to work, however, several conditions have to exist. First, and foremost, the medical marketplace must not be influenced by UCR itself, that is, this assumes that UCR merely reflects the medical marketplace, and does not play a large role in determining prices. Second, UCR assumes that provider pricing decisions are made independently, and that these decisions are based on factors such as the complexity of the service and the time that the service consumes.

Unfortunately, the conditions that are necessary for UCR to work effectively have never existed. Before UCR gained wide acceptance in the mid-1960s (which occurred primarily because of the use of UCR by Medicare) a marketplace of sorts may have existed, but a form of UCR is now used by so many health insurers that, to a certain extent, UCR is the marketplace. Providers are aware that since UCR bases today's payment on yesterday's charges, to receive more reimbursement tomorrow one must charge higher fees today. This was partly responsible for the ever-increasing escalation in charges to Medicare and other third-party payers over the past two decades. To combat this escalation in charges, in the 1970s Medicare tied reimbursement to an economic index to put an upper limit on the amount that could be paid for any one service. Over the years many charge profiles for individual services have reached this limit, meaning that rather than basing reimbursement on community charge levels, payment for many services is based on what is essentially a fee schedule with a built-in escalator for inflation.

Another feature of UCR payment is to acknowledge both the difference in seemingly similar services produced by different types of physicians, and the economic conditions in different areas. Thus, ideally, for any particular service there might be several UCR community fee profiles. For example, different fees might be paid to general internists and gastoenterologists for performance of an upper gastrointestinal endoscopy, and different rates paid to a gastroenterologists in Chicago and Houston. This assumes, however, that insurers have enough claims experience and data processing facilities to be able to actually compute fee profiles for many different physician specialties. In fact, very few health insurers have sufficient claims experience to actually calculate payment based on UCR. As described by Delbanco, et al., and Roe, the initial rate set for a new procedure is often based on charges submitted to Medicare carriers by relatively few physicians (Delbanco, Meyers, Segal, 1979; Roe, 1981). Because of the influence of these initial rates on charges by physicians in a community, the UCR-determined rate often approximates the initial (sometimes relatively high) rate, even as volume of use of the procedure increases greatly and is accompanied by economies of scale.

There are several different types of changes in current UCR physician reimbursement that Medicare might make. Perhaps the most likely is to eliminate different profiles for specialties and geographic areas. Thus, there might be one payment level set for a procedure for all physicians who perform the service in an area and/or physicians in different areas might be paid the same amount for the service. In the case of ESWL, it seems quite likely that only urologists will be performing the procedure for quite some time, and the procedure will be performed only in perhaps as few as 40 or 50 geographic areas. Thus, eliminating specialty and geographic area differences would have little effect on UCR payment for ESWL, unless, of course, geographic differences were eliminated entirely, with one rate established for the whole country.

If only a few urologists performed ESWL in an area, their claims would be the entire basis for UCR determination and they would essentially set their own rate of payment. If many community urologists performed ESWL, there would be many more physicians billing for ESWL, but each physician would bill for relatively few procedures. Even with many urologists billing for ESWL, it is difficult to conceive of this as the marketplace that is needed for UCR to operate properly.

The essential question is whether fees are set competitively, or whether there is an understanding among the physicians involved that a certain fee level should be maintained. With urologists performing the procedure at only two or three ESWL facilities in many communities, knowledge among physicians of general fee levels will be common. Thus, there is likely to be relatively little difference in fees between competing urologists. Given the often emergency conditions in which many patient first encounter their urologist, the variety of procedures that the urologist might perform, and the fact that few patients pay directly for most of their medical care, it seems highly unlikely that many patients would choose a urologist based only on the particular fee involved. (This is not meant to imply that physicians do, or would, collude; it is simply to point out that for many services performed by many different types of physicians the range of fees, and the patient's knowledge about and interest in fee levels, are so small that the competitive marketplace conceived of for UCR simply does not exist.)

The effect of changing UCR on the quality, access, and cost of ESWL for Medicare beneficiaries would probably be minimal. Whether or not UCR is changed to eliminate specialty and geographic differences in payment, patients will still be referred to the limited number of ESWL facilities available, and treated by the same urologists that would treat them today under current UCR.

Fee Schedules

Prior to the introduction of the UCR concept, fee schedules were the dominent method used by health insurers to determining reimbursement rates. The level of payment set in early fee schedules was based primarily on the amount of premium that the beneficiary was willing to pay. Since most commercial health insurance claims were paid on an indemnity basis, with the payment going to the patient who was then responsible for paying the provider, the beneficiary could choose different levels of premium, depending on their need for coverage.

With the growth of health insurance during the 1950s, it became apparent that methods were needed to standardize billing for services by physicians. One of the first organizations to address this need was the California Medical Association, which in 1954 published a "relative value study" or RVS. This RVS was based on a survey of physician fees in the community, and included two parts, a standardized nomenclature and a set of relative values attached to the nomenclature. Subsequent editions of the California Relative Values Studies (CRVS) were published, with each including more procedures and basing the calculation of relative values on charges prevalent in the community. (See Showstack, Blumberg, Schwartz, et al., 1979, for a more complete discussion of the development and uses of the CRVS and fee schedules in general.)

The CRVS became extremely influential in the health insurance industry, with many third-party payers (including Medicare) using the procedural terminology and often the relative values listed to determine payment level. For example, the California Medicaid (MediCal) program currently bases its payment to physicians on the relative values listed in the 1974 CRVS. The important point to note is that fee schedules used by third-party payers for medical care have been based either on the amount that the beneficiary was willing to pay for a policy, or on the fees charged in a community for individual services, but scheduled fees have essentially never been based on analyses of the costs of production of a service. The only exception to this might be the very unusual circumstances where a third-party negotiates with a provider, or providers, to determine a payment amount, such as is currently done by third-parties for certain tertiary care services.

Should Medicare change to a fee schedule method of paying physicians, the principal question for ESWL, and all physician services, is how the fee levels will be determined. Since it would be essentially impossible to assess the costs of production of all physician services, either community charge levels, or UCR payment limits, might be used to set fees. Although this would continue the protechnology bias in current physician payment, it has the advantage of stabilizing payment for all services at present levels (although increased volume of services can produce a rise in expenditures even if levels of payment for individual services are fixed.) Presumably the fee for ESWL would be set in much the same way that initial fees for new technologies are set now under the UCR system. A judgement of "comparable worth" would be made and the fee set at a level similar to other urologic procedures.

The key issue for ESWL and other procedures is not so much how the level of payment is set, but how high the level is. Unlike a UCR system, once an initial fee is scheduled it will not rise unless there is an active decision by the third-party to change the fee. The absolute level of payment is critical, however, to quality, access, and costs. Quality of care for Medicare beneficiaries would be reduced if the level of payment for ESWL were so low that the beneficiary's out-of-pocket costs caused the beneficiary to choose not to have the procedure. Likewise, if the payment were low, physicians might not accept Medicare patients. The relationship of the scheduled fee for ESWL compared to the scheduled fees for other urinary tract stone removal procedures may also produce incentives to perform one procedure rather than another. This would be particularly true if the urologist were to lose the fee by referring the patient to an ESWL center, in which case an inoffice procedure (of potentially lesser quality) might be chosen.

Several potential methods of calculating a physician payment level for ESWL are described elsewhere in this report. An addition step might be to periodically adjust the payment level chosen to account for changes in a variety of factors, such as general inflation, and in the costs of performing ESWL. These adjustments would, presumably, be based on aggragate data, and accounting for changes in marginal costs due to changes in volume of use of a lithotripter would be a difficult task. Other variations in the type of scheduled payments for ESWL are discussed below, particularly as they apply to payment for an episode-of-illness.

Paying Physicians for Care of an Episode-of-Illness

Another alternative payment mechanism (which includes certain aspects of both fee schedule payment and capitation payment) would be to establish a set amount of payment for care of an episode-of-illness. This concept assumes that illness occurs in discrete episodes that can be defined *a priori*, that are clinically logical, and for which a reasonable amount of payment can be defined. Similar in certain respects to capitation payment, where a set amount is paid to the provider for the care of a patient for a period of time (such as a month,) this alternative has several potential advantages. Limiting the amount that a third-party might have to pay, and creating incentives toward lower costs through putting the provider at risk for the amount of care provided, are among the most attractive features of payment by episode-of-illness.

Because urinary tract stones are generally discovered as a result of acute symptoms, which abate as the stone passes or is removed, urinary tract stone disease may offer an opportunity to pay for an episode-of-illness. Thus, when a patient first presents with hematuria and/or colic, and a new stone is discovered on x-ray, Medicare might pay a physician a set amount for all care of the patient until the stone passes or is removed. The generally limited nature of an acute episode of urinary tract stone disease makes this proposal a possible way to pay for care that might use ESWL, without having to decide on a specific rate of payment for ESWL.

What are the issues that would need to be resolved for Medicare to use this payment option? First, and perhaps most important, is the question of how the amount of payment would be set. An episode of urinary tract stones may begin with hematuria, little pain, and the discovery of a small stone. In such a case, the urologist would probably advise the patient to drink large amounts of fluids and return to the emergency room if severe pain was experienced. The acute symptoms may recede and the stone might remain asymptomatic for months or years. The urologist would have minimal involvement, except for assessing the patient and advising on followup care after the acute symptoms subside.

In a more typical example, the pain that results in the discovery of a stone might require admission to a hospital for analgesic treatment. If the stone appears to be passing (or able to pass) spontaneously, the patient might be discharged, only to be readmitted one or more times for symptom relief and, possibly, removal of the stone. In this case, the urologist might spend considerable time caring for the patient in the office and hospital over a period of weeks, and may perform surgery or ESWL.

A third example is a patient who presents in the emergency room with severe pain that is found to be caused by an impacted stone that is obstructing urine flow. The urologist would probably decide to remove the stone immediately by any one of several different techniques, which include ESWL. Finally, as noted elsewhere in this report, approximately

10 percent of patients who receive ESWL have second procedures in addition to ESWL.

Today payment to a urologist for caring for the first patient described above, from discovery of the stone to spontaneous passage in the first year, would range from approximately $100 to $500. If a procedure were performed to remove the stone, the payment amount for a year would increase to somewhat over $1,500. Payment to a urologist in the second example described above might range from $500 to several thousand dollars, depending on whether a procedure was used to remove the stone, while payment to a urologist in the third example would be mainly for the procedure, probably between $750 and $2,000. Thus, depending on characteristics of the case, today there might be as much as a 20-fold difference in payment.

If a single fee were established by Medicare to pay for an episode-of-illness, it would likely be based primarily on the most common type of care provided, which is illustrated by the second example described above. This would be a costly choice, since the most common is also the most expensive. An average fee, on the other hand, would provide an incentive for a urologist to intervene and remove the stone quickly and be done with it. To avoid these problems, different types of stones and different types of episodes might be defined and a seperate amount paid for each category. This process of differentiation, however, is exactly what a "packaging" physician payment option is supposed to avoid.

Other issues that would have to be dealt with in packaged payment are the discovery of multiple stones that eventually pass at different times, the discovery of an asymptomatic stone incidental to an radiology exam performed for other reasons, and the performance of procedures in addition to ESWL. Of most importance to the use of ESWL, however, is the question of what happens when a patient is referred from one physician to another, such as when a community urologist refers a patient to an ESWL facility. Would the fee be divided among the various physicians involved? If so, who would decide on what basis the division would be made? Dividing fees in this way might even be considered to be fee-splitting, which is illegal.

Finally, the passage of a symptomatic stone does not cure stone disease. The majority of persons who present with a first stone eventually develop other stones. Payment would have to be made for the continuing care of patients after the acute episode is over. Thus, even though urinary tract stone disease appears to present discrete episodes-of-illness, more so than do many other common diagnoses, there is sufficient variability in the types of episodes that are common that arriving at the "appropriate" payment amount may be a difficult task.

If a payment rate is set for an episode-of-illness, it is likely to be lower than the typical payment for an average episode of care today that includes ESWL. This could have several potential effects. First, it would provide an incentive to perform other less costly procedures instead of ESWL (since the cost would be borne to a certain extent by the physician.) Second, payment by episode might provide an incentive to perform an inoffice procedure rather than refer a patient to an ESWL center. To the degree that ESWL is the preferred procedure in a particular situation, incentives to perform procedures other than ESWL might produce lower quality care.

Similar to the option where a physician is paid to care for an episode-of-illness, the episode might be broken down into an ambulatory segment and a hospital segment for purposes of payment. This would have the advantage of paying community urologists separately for office care if the patient is referred to an ESWL center. There would still be negetive incentives in this option, however, such as encouraging a physician to refer a patient to another physician, or tertiary care center, and still be able to charge for a "routine ambulatory care" episode.

The division of an episode-of-illness into ambulatory and hospital segments does not describe well the typical episode-of-illness of a patient with urinary tract stones. For example, when a patient is deemed to be a candidate for ESWL or a surgical procedure, the patient is usually seen in the urologist's office first for an examination, then admitted to the hospital for the procedure, finally to be seen again by the urologist in the office post-discharge. The amount of time spent with the patient in each setting would depend in large part on the severity of the patient's condition and speed of recovery from the procedure.

Thus, urinary tract stone disease has certain characteristics that make it an attractive candidate for the use of an option to pay physicians based on care of an episode-of-illness. Even this diagnosis, however, presents substantial problems for the use of this payment option. Of particular importance are potentially perverse incentives that payment for care of an episode-of-illness might produce, including incentives that could result in a patient receiving lesser quality care than might otherwise be given, with no guarantee of any cost-savings to the third-party. Key organizational and technical issues would also have to be addressed, such as defining an episode-of-illness, deciding to whom payment will be made, and determining the rate of payment.

Adjusting Payment as Costs Change

The acquisition costs of ESWL (around $1.7 million) cause the cost per procedure to be relatively high, at least in the first few years of use. Eventually, however, capital costs are paid-down and there is a potiential that the cost of operating the equipment will consist mainly of the lower costs of supplies, maintenance, space, etc. Also, manufacturers other than the Dornier Corporation might produce lithotripters, creating competition that lowers its acquisition costs. In these cases, it might be possible to adjust downward the payment for the technical fee for a high capital-cost technology such as ESWL.

While theoretically appealing, there are a variety of difficult issues that a third-party payer would have to address should it wish to tie payment more closely to costs. The payment system has tended to avoid adjusting payment to match costs for individual services for both professional fees and hospital charges. For example, physician payment for coronary artery bypass graft surgery has risen despite greatly increased efficiency in performing the procedure (Roe, 1981).

How to measure the marginal costs of providing a particular service, and how to disentangle the step-down indirect cost-accounting methods used by hospitals, are other issues with which third-party payers have little experience (Finkier, 1982). Perhaps the most difficult issue in cost-accounting in a hospital is to differentiate the joint-products that are produced. For example, when ESWL is provided in a large community hospital to an indigent patient, the products of the service include treatment of the patient, and, perhaps, community service, teaching of medical residents, and research on the effects of ESWL. Most third-party payers in the past have implicitly allowed the costs of products other than treatment to be included in the patient's bill. Even today, for example, Medicare pays for graduate medical education along with care of patients in teaching hospitals.

There are also other reasons that payers have been reluctant to lower payment. First, lower payment by a third-party for physician services may simply put an additional burden of payment on the patient. Since most health insurance is purchased, or provided, through mechanisms that spread the cost over many individuals (such as that purchased by large corporations for their employees and that provided by the government to Medicare beneficiaries) often the main out-of-pocket cost that patients incur is for paying the difference between what an insurer will pay and what the provider charges. If charges continue to rise, but third-party payment does not, the burden of paying the higher cost may rest mostly on the patient. The patient may well take his health insurance business elsewhere. In the case of Medicare payment, were payment to be lowered, but charges by the physician were to remain the same (assuming that the physician does not accept assignment), many elderly patients would simply end up paying the physician a larger amount. Similarly, lower payment by a third-party may alienate the physician.

Thus, third-party payers for medical care would rather pass on higher costs to large-group purchasers of insurance than incur the animosity of individual patients and physicians. Until recently, most large purchasers of health insurance have paid the higher charges for health insurance with little argument. As the climate shifts to more competition and a desire for lower costs, third-party payers are presented with a situation in which they have very little experience, that of actively deciding on the rate of payment for a service, rather than being simply a pass-through for funds from the patient to the provider.

Finally, there is the basic issue of technology obsolescence. In the time that it takes to pay for a high cost technology, perhaps as short as three years, newer versions of, or substitutes for, the technology may be developed. As these newer technologies may have lower acquisition and/or operating costs, payment might be adjusted to take advantage of these lower costs. This is essentially what happens as newer technologies replace older technologies (e.g., ultrasound as it replaces invasive x-rays.) New technologies will go through the same approval process that the older technologies went through, and rates of payment for their provision will be determined by payers in much the same way that rates were decided in the past.

A detailed description of hospital cost-accounting methods is beyond the scope of this report, but suffice it to say that the complexities of cost-accounting in medical care have lead most third-party payers, including Medicare and Medicaid, to almost totally avoid this issue in the past. One of the many reasons that prospective payment is so attractive to many payers for medical care is that it puts the burden of assessing the costs and benefits of individual services almost totally on the provider. Thus, although lowering payment for ESWL as costs decrease is possible, it would require third-party payers, including Medicare, to enter into a whole new arena of payment - one that many third-party payers are actively trying to avoid by paying for care prospectively.

Payment Based on the Major Services Used

Another way to define a medical care "product" is to base the definition on the major procedure or services used. In a sense, this is what DRG hospital payment is. Medicare, for example, pays a hospital a predetermined amount for the care of a patient provided with surgery, basing the amount of payment in large part on what type of surgery is provided.

The generic problem with this type of payment is exemplified by the variety of therapies available to treat urinary tract stones, and the lack of specific indications for choosing one type of therapy rather than another. For example, it might be possible to determine an amount of payment to a physician for performance of a particular urologic technology. Without explicit indications for one procedure rather than another, however, differential payment (defined by procedure) would produce large economic incentives to perform the procedure that has the highest marginal return.

These potentially perverse incentives exist today under Medicare prospective payment. For example, payment to a hospital by Medicare for a patient who is given medical treatment for a urinary tract stone is substantially less than if that patient is provided with a surgical intervention. Even assuming that clinical considerations are the dominant reason for the choice of treatment, the financial incentives may have an effect, at the margin, on choice of treatment.

Paying physicians based on the major service or technology provided may be more difficult to construct and implement than prospective payment for hospitals. The amount paid for an admission for urologic surgery in a particular hospital is based, in a simplified description, on the average amount charged for treating a patient with a particular diagnosis in other hospitals. In contrast to paying hospitals for a discrete admission, for physician payment a "surgical" service includes care before, during, and after the hospitalization, essentially a package of care. Thus, a change to procedure-based payment might be similar to current physician payment, except for one major difference: presumably non-surgical treatment of urinary tract stones would have to also be defined as a package. The major difference between this payment alternative and what exists today is that the amount of payment would be set prospectively, and payment for medical treatment would also be for a "package" of care. (Issues surrounding "packaging" as a physician payment alternative are discussed above.)

Capitation Payment

When attempting to contain costs, some payers have recently implemented two methods of physician payment that are quite different from traditional fee-for-service payment: capitation and preferred provider contracting.

Capitation payment is discussed here, while preferred provider contracting is discussed in the next section.

Capitation payment is an agreement between a provider (generally a group of physicians and/or hospitals) and an insurer to provide all necessary care to a beneficiary for a period of time for a prospectively set fixed payment. (Certain services, such as long-term care, dental care, and optical care are often excluded.) The attraction of capitation payment is that it limits the amount of payment by the third-party payer, while it puts the provider at financial risk for excessive use of services. Because it reverses the incentives in the fee-for-service system, which encourage relatively unlimited delivery of services, there is a danger in a capitation system of too little care being delivered, although there is little evidence of this happening (Luft, 1978).

The principal form of capitated systems are health maintenance organizations (HMOs), which have been shown to hospitalize patients up to 40 percent less than fee-for-service care (Luft, 1981). Generally, HMOs agree to provide a relatively complete array of services for the capitation payment, but other arrangements are possible. It is conceivable that a payer, such as Medicare, could contract with (a) provider(s) for certain tertiary services. For example, Medicare currently pays renal dialysis centers on a capitated basis to care for patients with end-stage renal disease.

A group of urologists might agree to provide all necessary urologic care to a set of Medicare beneficiaries for a fixed payment. If the urologists were not associated with an ESWL center, the burden of paying the center for ESWL would fall on the urologists rather than Medicare. A potentially significant problem with this alternative is that the incentive to refer to the ESWL center would depend on the agreement between the center and the urologists; that is, Medicare would have little control over access to ESWL. A solution to this problem might be to contract directly with ESWL centers, and urologists associated with them. A broader solution might be to contract with HMOs for a full array of services, including urologic care.

The primary limiting factor in capitated care for Medicare beneficiaries is the relatively few HMOs available. Although HMOs have been encouraged by federal law since 1972, their growth has been disappointing. The prinmary reason for this slow growth is the reticence on the part of providers, patients, and payers to leave the fee-for-service system, which allows greater choice in the selection of providers and services than does capitated payment. The potential reduced access to providers, and the risk of underservice, are the primary issues that must be addressed should Medicare consider capitation as an alternative physician payment method.

Preferred Provider Contracts

With the recent emphasis on competition in health care, there has been increased interest in ways that third-party payers can contain costs through encouraging the use of efficient providers. The development of preferred provider organizations (PPOs) is a step in this direction (Trauner, 1985). In a PPO, providers agree to accept negotiated fees, based on the expectation that more patients will use their services. Patients who choose a PPO health insurance option usually can elect to see a PPO physician or a non-PPO physician. The incentive to the patient to see a PPO physician is generally greatly reduced (often zero) cost-sharing, whereas out-of-pocket costs for a visit to a non-PPO physician might be substantial (Trauner, 1985).

Preferred provider organizations are usually thought of as including a full array of physician specialties, but other arrangements are possible. A health insurer might contract with, or limit payment to, only one or a few providers of a specialized service. For example, much of neonatal intensive care is paid for in this manner.

Extracorporeal shock wave lithotripsy has many characteristics that make it a possible candidate for preferred provider contracting by Medicare: ESWL is a tertiary care service, limited in availability, with cost very sensitive to volume of use, and will soon be part of standard urologic care. It is very likely that most ESWL centers will be eager to contract with third-party payers, since the additional patients may be enough to make the difference between solvency and insolvency. At the same time, preferred provider contracting allows Medicare beneficiaries to go to other ESWL centers if they are willing to pay the higher costs. Quality of ESWL treatment is likely to be high at the contracting center.

The one possible drawback to preferred provider contracting for ESWL services is that it will limit the choice of community urologists in their referral decisions, and may also make it difficult for community urologists to provide ESWL treatment themselves. Paying an equitable fee to community urologists who refer patients to an ESWL center may need to be considered if this alternative physician payment mechanism is to be used by Medicare.

For ESWL, the principal difference between a capitation contract and a PPO contract is that, generally, the former pays for all care for a set of patients while the latter pays for each ESWL as it is provided. Both methods would limit Medicare's financial risk, with some potential costs to beneficiaries.

Summary

There are a variety of ways that Medicare physician payment might be changed. Changes in UCR to eliminate specialty and geographic differences would have the least effect on the use of ESWL of any of the main physician payment alternatives, primarily because of the limited variability in physician specialty and geographic characteristics. The use of a fee schedule might have significant effects on quality, access, and costs, depending on the level of the fee paid. Packaging alternatives are attractive, but require the development and application of definitions of episodes-of-illness, a difficult task at best. Lowering payment to match declining costs would require the development of new methods to quantify the average and marginal costs of the performance of ESWL. In the past, third-party payers for medical care have not attempted to set payment levels on the basis of the actual costs of production of individual services; the lack of experience of health insurers and lack of available methods to disentangle the multiple products produced in the provision of medical care services make this an unlikely alternative. Capitation is an attractive alternative because it puts the responsibility for cost-savings on the provider. There may not be enough health maintanence organizations and other capitated systems available to Medicare across the country to negotiate many full-service capitation contracts, but Medicare might sign capitation contracts with ESWL centers. Preferred provider contracting, on the other hand, would allow Medicare to use its market power to purchase ESWL at both a low cost and to guarantee access for Medicare beneficiaries to ESWL.

Overall, perhaps the most important factor that will affect quality, access, and costs is the price that Medicare is willing to pay physicians to perform ESWL. The calculation of the payment level, and possible negotiations with ESWL providers, will have to be undertaken with a sensitivity to the potentially large effects on quality, access, and costs that a small change in payment levels might have.

Future Use of ESWL: Unresolved Issues

It is too early in the development and use of ESWL to predict accurately the future contribution of ESWL to the treatment of upper urinary tract stones. The ultimate judgment about the cost effectiveness of ESWL will be based, in large part, on the answers to several questions.

Unresolved clinical issues will have a large influence on the future of ESWL. In particular, there are questions regarding the effect on the kidne of multiple ESWL treatments, the possible deposit in the kidney of small stone fragments that remain after ESWL treatment, and the overall criteria for using ESWL.

The kidney is a delicate organ. Although ESWL appears to be a relatively safe procedure, the fact that gross hematuria accompanies ESWL treatment implies that a certain amount of damage is being done to the kidney by the procedure. Since many patients have multiple recurrences of urinary tract stones, and since ESWL has yet to be repeated after a period of time on patients with second stones, the long-term effects of multiple procedures is not yet clear. Second, small pieces of stone are created by ESWl destruction of urinary tract stones. This "stone dust" may lodge in a kidney and provide "seeds" for the development of new stones. Thus, there is a possibility that ESWL may actually increase the incidence of stones in patients who receive this procedure. Finally, as mentioned earlier in this report, the development of criteria for the use of ESWL will go a long way toward the resolution of the question of whether ESWL is cost effective. In particular, criteria are needed for the use of ESWL for stones that are not producing particularly morbid symptoms and that are likely to pass spontaneously after a period of time.

Several economic issues also need to be addressed. The development of less expensive alternative methods of treating upper urinary tract stones, and, possibly more importantly, of preventing stone formation, will have large effects on the economics of ESWL. Because of the high costs associated with the provision of the procedure, any reduction in volume of use of the facilities will cause costs per procedure to rise considerably. Another key economic issue is who purchases the lithotripter. The economic consequences of a nonprofit hospital purchase of a lithotripter are substantially different from the consequences of a physician or group of physicians purchasing a lithotripter, due primarily to different tax structures. In particular, any revision in the income tax code toward the deletion of the investment tax credit might affect the economics of ESWL substantially. Finally, the site of the performance of ESWL (i.e., outpatient or inpatient) has major consequences for overall payment for the procedure.

There are a variety of organizational issues that are unresolved regarding the use of ESWL. Of particular importance is the relationship between community urologists and the local ESWL center. Will community urologists refer patients to the ESWL center? What criteria will be used for referral? How willing are community urologists to transfer care of patients to the ESWL center? (We estimate that, on average, urologists provide between 20 and 40 procedures per year for urinary stones in the upper urinary tract. This probably equals gross yearly charges in the range of $20,000 to $40,000. Thus, community urologists would be incurring a substantial financial loss by referring all of their patients with upper urinary tract stones to an ESWL center.)

Extracorporeal shock wave lithotripsy appears to be a useful new technology that is likely to become the standard of care for the treatment of many types of upper urinary tract stones. The future of ESWL depends, however, on a variety of clinical, economic, and organizational factors, many of which are beyond the direct control of either clinicians, patients, payers, or policymakers.

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APPENDIX

A NOTE ABOUT COST ESTIMATES

The one year salary of $175,000 that is used in the calculations in Table 4 is based on the approximate rate of earnings of a general surgeon as reported by the American Medical Association. In 1979, the most recent year for which data are available for urologists, the median net income for general surgeons in solo practice was $96,000 and the median net income for urologists in solo practice was $93,530, and in partnership was $99,060 (AMA, 1981). Based on the reported rate of rise in general surgeons' incomes through 1982, the appeoximate median net income of a general surgeon in 1985 is $175,000; thus, this figure was used as an approximation of a urologist's median net income in 1985 (Reynolds, Abrams, 1983).

It is important to note, however, that the salary of $175,000 for both general surgeons and urologists incorporates the fee-for-service system's procedural bias, in which time spent on providing procedures and technologies is reimbursed much more highly than is time spent providing non-technological care (Almy, 1981; Schroeder, Showstack, 1978; Showstack, Schroeder, Steinberg, 1981). To the extent that the procedural payment bias is justified, then the hourly rate of pay for ESWL of approximately $136 ($175,000 salary plus $43,750 fringe benefits for a total of $218,750 divided by 1610 work hours in a year, Table 4) is appropriate. If one wishes to create a more "procedure-neutral" reimbursement system, however, one might consider that an hourly rate based on the earnings of physicians who provide only some technological care, such as general internists, would be a better approximation of the "worth" of the time taken to perform ESWL (in other words, about $85 per hour). The higher figure was used to point out that even projecting a net income of $175,000 per year yields physician costs for performing ESWL that are less than one-half of the charge being proposed by urologists (about $1,600 per procedure).